

Addressing the pipeline and access crisis for antibiotics

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**GLOBAL LEADERS GROUP
ON ANTIMICROBIAL RESISTANCE**



1. The antibiotic pipeline and access crisis

The antibiotic pipeline and access crisis

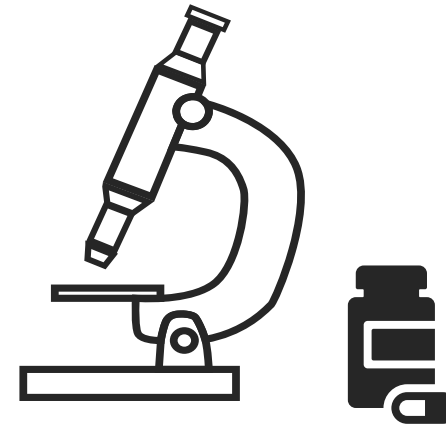
The lack of access to existing and innovative antibiotics is a contributor to the inappropriate use of antibiotics and the development of AMR.
The pipeline and access crisis is delineated by:



- Diminishing effectiveness of current antibiotics



- Limited global access to antibiotics (novel and generic)

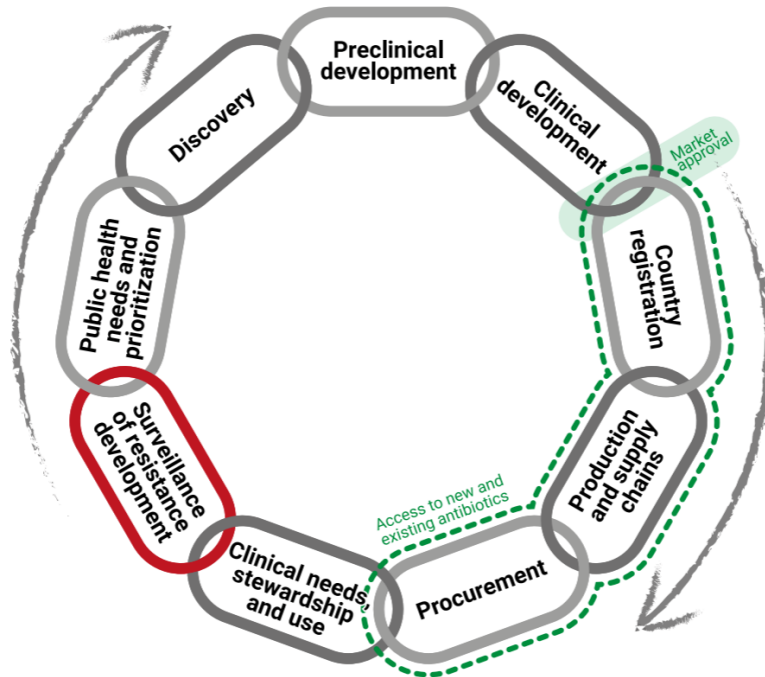


- An insufficiency in research and development (R&D) for innovative antibiotics needed to treat drug-resistant infections

R&D and access chain

Ideal...

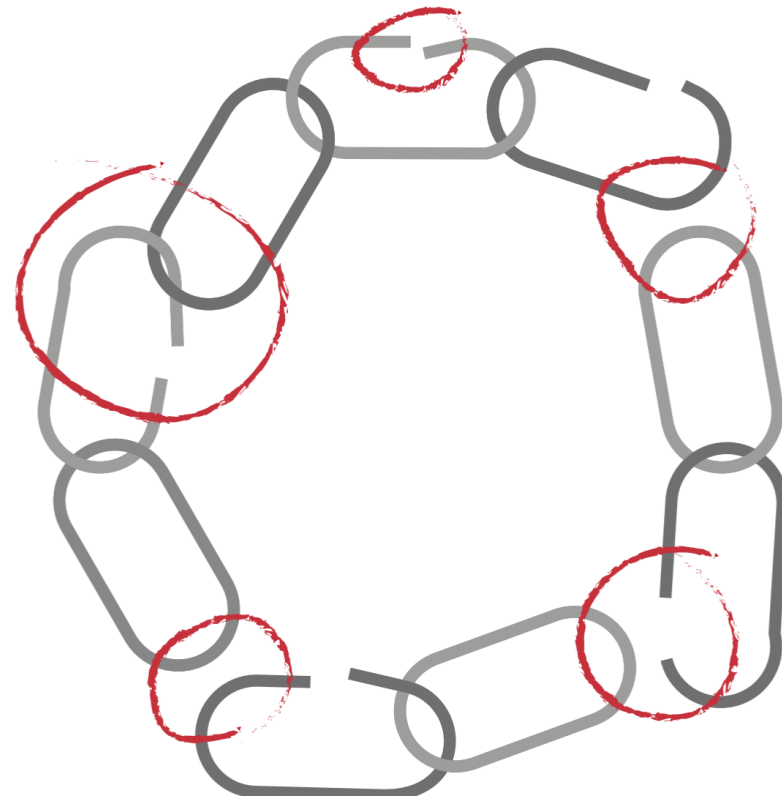
The antibiotic Research & Development and Access chain



High-Level Meeting on Antimicrobial Resistance 6

Reality...

The **fragmented** antibiotic Research & Development and Access chain

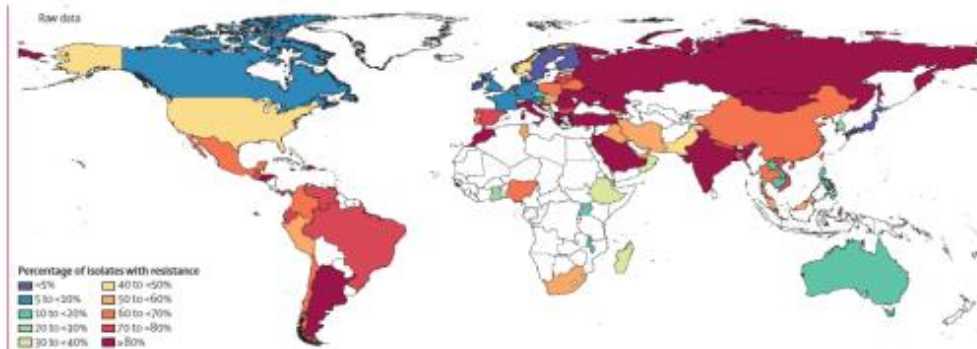


Source: Swedish Ministry of Health and Social Affairs

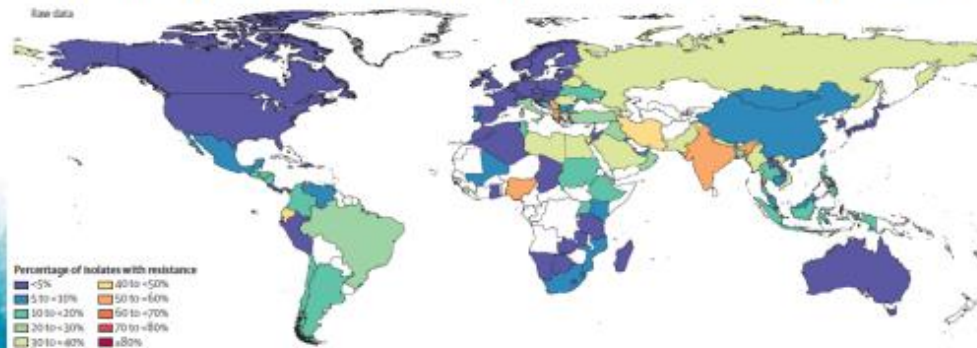
Three trends in antibiotic access

1. Growing antibiotic resistance

Carbapenem-resistant *Acinetobacter baumannii*

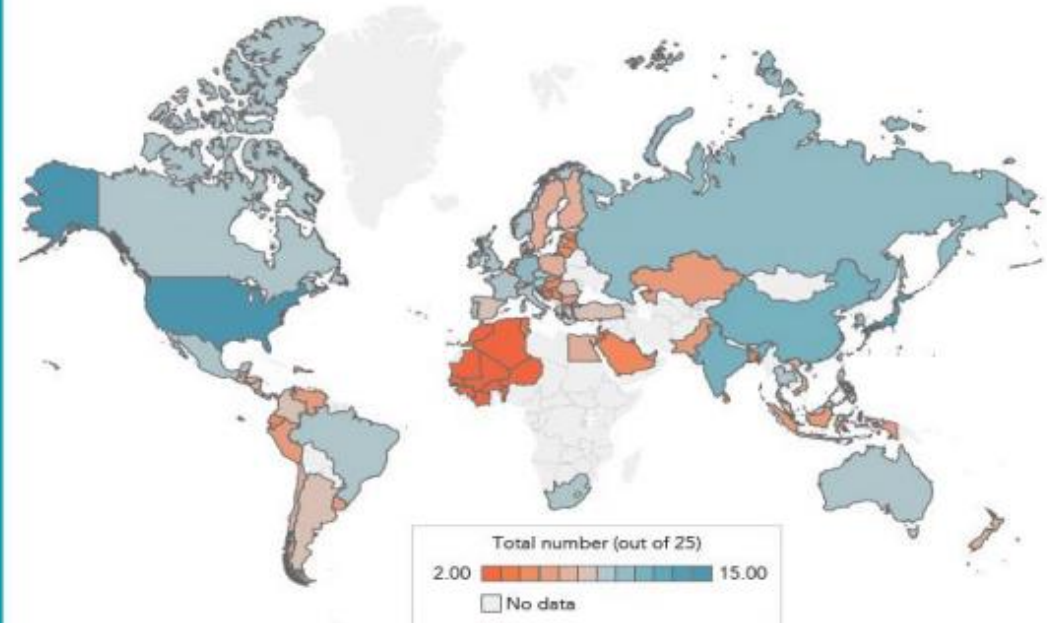


Carbapenem-resistant *Klebsiella pneumoniae*



2. Not widely registered

Number of antibiotics registered 1999-2014



3. Affordability of Antibiotics and Diagnostics

2. Addressing the antibiotic pipeline and access crisis

Overarching solution

Access to effective antibiotics is a global public good; it should not be left to market forces. Stimulating R&D and safeguarding access requires collective action across a range of mutually reinforcing interventions (financial and nonfinancial) to maneuver through the challenges and construct resilient, equitable systems.

Long term, predictable financing is needed to achieve robust R&D and global access



Financing must be accompanied by a set of complementary interventions that cover the end-to-end value-chain



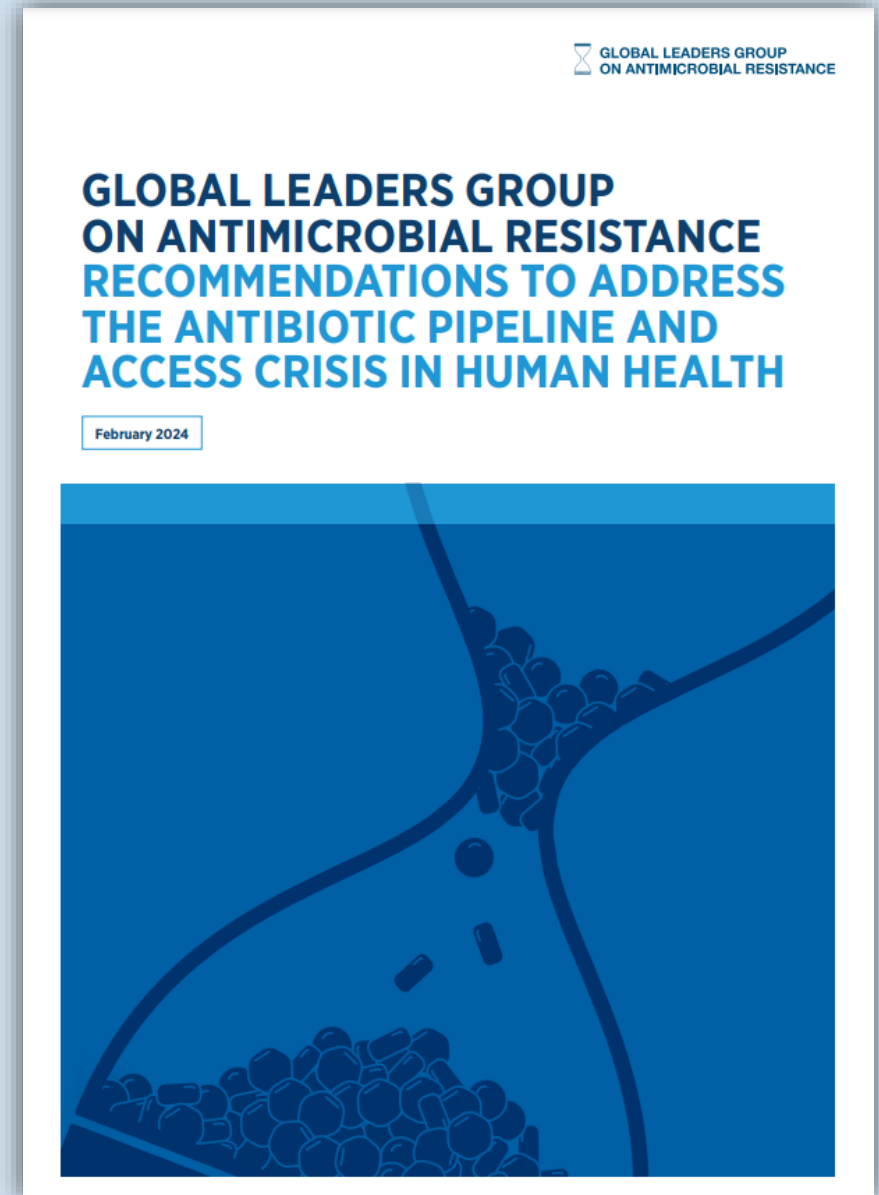
Coordination and cooperation bringing together the capabilities of the public and private sector

The focus is the antibiotic R&D and access crisis, and it should be seen as part of comprehensive AMR action that includes surveillance, stewardship, evidence-generation efforts on the burden of AMR disease and a clear economic case for investment. As well as a movement comprised of all facets of society, activated, and nurtured by the sharing of evidence, information, and human-centered storytelling that drives political will. R&D and Access to antibiotics have key dependencies with these topics, but this paper refrains from covering them in depth.

3. GLG recommendations to address the antibiotic pipeline and access crisis in human health

Six recommendations for global action across a range of financial and nonfinancial solutions.

- Proposed for consideration of Member States for the High-level Meeting on AMR on 26 September 2024
- To help transform the recent G20 and G7 commitments around R&D and access into action
- To catalyze collective, global action



RECOMMENDATION 1

Working with governments, industry and other key stakeholders, WHO should lead the establishment of global shared R&D targets for antibiotics and diagnostics for human health, with implementation roadmaps and TPPs.

Context

- R&D for novel antibiotics down 81% in recent years
- Well-defined targets can anchor R&D ecosystem and facilitate funding and collaborative action

How can this be achieved?

- Start with WHO priority pathogens list
- Base on understanding of pipeline and projected longevity of existing medicines
- Set on transparent prioritization criteria
- Establishing R&D roadmaps with strategic plans
- Action among agencies involved in clinical trials and regulation

RECOMMENDATION 2

Public and private funders/donors should increase funding for push incentives that support the development of antibiotics and diagnostics.

Context

- Few preclinical antibacterial agents make it to clinical development
- Products in clinical development rarely target “critical” bacteria and fulfill innovation criteria

How can this be achieved?

- Align push incentives with R&D targets and roadmaps
- Strengthen and diversify R&D efforts – including researcher and developers from LMICs
- Ensure incentives include equitable access strategies and target R&D ecosystem (particularly LMIC developers)
- Increase funding for non-traditional agents and non-therapeutic interventions

RECOMMENDATION 3

The G7 and G20 should each play their role in establishing pull incentives to support R&D and enable access to antibiotics and diagnostics.

Context

- Holistic incentive package –including pull mech. needed to achieve R&D targets
- Pull incentives reward successful development and access
- Provisions for global/LMIC access are largely absent from current mechanisms

How can this be achieved?

- Building on current momentum created by international efforts
- Explore equitable access-focused mechanism targeting LMICs
- Explore additional pull incentives for diagnostics
- Ensure mutually agreed terms and transparency in pull incentive contracts between manufacturers and governments

RECOMMENDATION 4

National and regional regulatory bodies should adopt regulatory frameworks to facilitate development and regulatory approval of antibiotics as part of their efforts to achieve a regulatory system maturity commensurate with a stable, well-functioning and integrated regulatory system for medicines and diagnostics (WHO maturity level 3).

Context

- Streamlining of regulatory frameworks needed to enable timely release of new products
- Collaboration (regional & global) key to avoid duplication of efforts

How can this be achieved?

- Streamline product registration, consider revising registration fees for certain products
- Evaluate & respond to regulatory systems gaps
- Harmonize efforts to accelerate regulatory approvals
- Establish regulatory pathway and frameworks for diagnostics

RECOMMENDATION 5

National governments, WHO, partners, and donors should significantly expand efforts to increase access to essential antibiotics and diagnostics while ensuring their appropriate use.

Context

- Access challenges: Shortages, Forecasting, Financing, Inappropriate use, fragile Supply chains
- Take years before LMICs have access to successful diagnostic and antibiotic innovations

How can this be achieved?

- National government action: Sustainable financing, Strengthen supply chains, Simplify antibiotic portfolios, Target antibiotics to right patients, Introduction strategies for new products
- Supranational action: Support LMICs → equitable access, Diversify manufacturing
- Manufacturers: implement goal access strategies and strive for sustainability

RECOMMENDATION 6

Strengthen global coordination across the R&D and access continuum, building on existing fora and partnerships.

Context

Current ecosystem lacks: Shared agenda , End-to-end strategic orientation, Oversight & coordination, Transparency for national and supranational actions

How can this be achieved?

- Ensuring monitoring for progress of R&D targets and roadmaps
- Pull Incentive Hub, Access coordination and LMIC support, Public-private collaborative platform
- National AMR accountability mechanisms

Conclusion

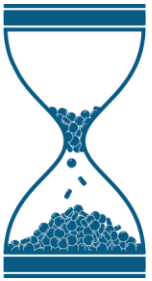
To address Pipeline and Access crisis...

1. Establish shared R&D **targets**
- 2/3. Enhance push and pull **incentives**
4. Regulatory bodies should **facilitate R&D**
5. Expand **access**, ensuring appropriate use
6. Strengthen global **coordination**

2024: Fora to implement change

- UNGA HLM on AMR
- 4th Ministerial Conference on AMR





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