Financing – Antibiotic R&D for Better Access in LMICs

International Workshop on LMIC Priorities to inform 2024 HLM on AMR

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The Quadripartite Joint Secretariat on AMR

**Purpose:** Consolidate cooperation between FAO, UNEP, WHO and WOAH drawing on their core mandate.

**Hosted** by WHO with full time liaison officers in FAO, WOAH and UNEP

**Manages** the daily activities of the joint work of the organizations across One Health

**Functional arrangement** established following a request by UNSG in October 2019

- Support global promotion, advocacy and political engagement
- Support to Global governance structures (Global Leaders Group and Partnership Platform)
- Coordination and monitoring of Quadripartite Strategic Plan and workplan implementation and mapping gaps & opportunities
- Coordination and partnership
Catalyzing Global, Regional and Country Political Momentum for AMR Response

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R&D and access chain

Ideal...

The antibiotic Research & Development and Access chain

Reality...

The fragmented antibiotic Research & Development and Access chain

Source: Swedish Ministry of Health and Social Affairs
Clinical pipeline for ABx is fragile & insufficient to meet global AMR challenge

- Lack of public health relevance/disconnect in some R&D projects
- Challenges in recruiting patients for clinical trials
- Financial difficulties - Retreat of large pharmaceutical firms from ABx market, financial difficulties for small and medium-sized enterprises
- Inadequate surveillance systems
- Supply chain challenges
- Gaps in diagnostics, lab infrastructure, and skilled human resources – esp. in LMICs
Two trends in antibiotic access

1. Growing antibiotic resistance
   Carbapenem-resistant *Acinetobacter baumannii*

2. Not widely registered
   Number of antibiotics registered 1999-2014
Approach

**Literature review**
- Review of published and grey literature
- GLG presentations, deliberations & statements
- Deep dives on key topics
- 59 references

**Interviews**
- GLG members (14)
- Additional experts and stakeholders (12)

**Discussion Paper**
- Prof Antonio Correia de Campos
- Prof Onyebuchi Chukwu
- Prof Dame Sally Davies
- Dr Maggie De Block
- Dr Chris Fearne
- Mr Jakob Forssmed
- Dr Jamie Jonker
- Prof Dr Ernst Kuipers
- Ms Sunita Narain
- Mr Paul Schaper (in lieu of Jennifer Zachary)
- Dr Mark Schipp
- Mr Yasuhiisa Shiozaki
- Dr Scott Weese
- Prof Lothar Wieler
- Michael Andersen (LSE)
- Akhil Bansal (Schmidt Futures)
- Peter Beyer (GARDP)
- Lesley Ogilvie (Global AMR R&D Hub)
- Kevin Otterson (CARB-X)
- Jessica Martinez (BMGF)
- Ben Park (Global Fund)
- Jean-Baptiste Perrin (EU HERA)
- Dave Ripen (CHAI)
- Padmini Srikantiah (BMGF)
- Keith Sumption (FAO)
- Javier Yugueros-Marcos (WOAH)

Financial and non-financial solutions to the R&D and Access crisis
Global Leaders Group on AMR mobilized to address the antibiotic pipeline and access crisis

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

https://www.amrleaders.org/resources/m/item/glg-recommendations-to-address-the-antibiotic-pipeline-and-access-crisis-in-human-health
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
Thank you

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https://www.qjsamr.org/