PRIORITIES OF LOW- AND MIDDLE-INCOME COUNTRIES (LMICs)

TO INFORM THE HIGH-LEVEL MEETING ON AMR AT UNITED NATIONS GENERAL ASSEMBLY 2024

Key takeaways based on proceedings of an international workshop for LMICs
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INTRODUCTION
In September 2024, the silent pandemic of antimicrobial resistance (AMR) will be discussed among Member States at the High-Level Meeting (HLM) on AMR in the United Nations General Assembly. Ambitious and specific commitments are expected for future global action. It is important that HLM is adequately informed about priorities of low- and middle-income countries (LMICs) that are expected to be heavily impacted by AMR, but have limited resources and also different drivers and solutions.

Recognising this need, Centre for Science and Environment (CSE) organised a two-day international workshop in India in April 2024. The workshop brought together over 45 experts, mostly from the LMICs. They included AMR focal points from
13 countries in Africa and Asia, stakeholders from global civil society, inter-governmental organisations, and research and scientific bodies across human-health, animals, crops and environment sectors.

Experts discussed the realities and priorities of the Global South on issues such as financing for One Health AMR action plan implementation in LMICs; financing for antibiotic R&D and access in LMICs; food systems transformation and the ‘preventive approach’ to sustainability; managing antibiotic pollution from manufacturing and the ‘access’ lens; and target setting, their enablers and challenges in LMICs.

This report presents the key takeaways from the deliberations held at the workshop.
A SUMMARY
OF THE KEY
TAKEAWAYS
FINANCING FOR ONE HEALTH AMR ACTION PLAN IMPLEMENTATION IN LMICs
• National AMR action plans are critical for local action, but are impacted by dependence on donor funds which need to be optimised.
• Domestic funding must be mobilised for sustainable action against AMR.
• National action plans should be costed, prioritised and multi-sectoral, yet integrated.
• National action plans and their implementation mechanisms should be made fit for the purpose.

FINANCING FOR ANTIBIOTIC R&D AND ACCESS IN LMICs
• Prioritisation of interventions and investments in antibiotic R&D should be based on public health needs, including those of LMICs.
• Improving access must be integral to antibiotic innovation financing and interventions.
• Access to old and new antibiotics remains a big concern in LMICs which must be addressed systematically.
• Regulatory harmonisation is needed for early access, but new antibiotics should be introduced in a controlled manner by governments.
• Financing mechanisms need to go beyond push-and-pull and reflect a balance in public-private partnership.
• LMICs can become the first choice as a hub for antibiotic development.

FOOD SYSTEMS TRANSFORMATION – THE ‘PREVENTIVE APPROACH’ TO SUSTAINABILITY
• Antibiotic reduction is possible in intensive food-animal production systems through preventive measures and alternatives.
• Preventive solutions will make food systems sustainable; they should be cost-effective or incentivised to enable upscaling.
• Food systems need to be transformed holistically and made sustainable.
MANAGING ANTIBIOTIC POLLUTION FROM MANUFACTURING AND THE ‘ACCESS’ LENS

• Growing global momentum to curb antibiotic pollution from manufacturing is leading to government and industry action: this needs to be strengthened and expanded.
• Compliance to discharge limits is resource-intensive and needs to be approached systematically to avoid the ‘access’ crisis.

TARGET SETTING – DIFFERENTIAL TARGETS FOR LMICs, THEIR ENABLERS AND CHALLENGES

• Targets are needed and should be differential for countries. LMICs must unite to prioritise the prevention interventions for greatest impact on mitigating AMR.
• LMICs need to identify enablers and challenges and build on them to meet the targets.
FROM
SUNITA NARAIN
LMICs are facing multiple challenges
“There is a need for increasing access to healthcare and life-saving medicines. There is also a need to increase food productivity and ensure farmer security. At the same time, LMICs cannot afford the high cost of cleaning up after contamination or the high cost of medical treatment when basic drugs like antibiotics will not work. LMICs cannot afford antibiotic resistance.”

To address the multiple crises, LMICs need to do things differently. Solutions have to be different, bold and transformational
“There is a need to leapfrog and reinvent pathways for growth without pollution. This will require serious reinvention on the way we do business with our food and environment.”

The High-Level meeting at UNGA 2024 is an opportunity to bring the world together on the issue of AMR which will need global cooperation and action
“It is time for LMICs to take ownership of the AMR issue and reframe the roadmap for action that would work for them.”
The agenda for reinventing should focus on conservation, development, environment and prevention

“The ‘conservation agenda’ is about ensuring that antimicrobials critically important for human health are not used in livestock and food, more so because the ‘pipeline’ for new antibiotics is dry. The ‘development agenda’ is about ensuring that we can continue to increase food production without or with reduced use of chemicals, including antibiotics. The ‘environment agenda’ is about ensuring that the waste from pharmaceutical and other sources is tracked and contained. But most importantly, the ‘prevention agenda’ is about preventing pollution and overuse of chemicals.”

‘One Health’ is planetary health for all

"In the context of AMR, there are different pathways contributing to it — such as overuse of antibiotics by humans, their use in growing food from livestock, or the waste contaminated with antimicrobials from the pharmaceutical industry, the intensive poultry industry or sewage treatment plants. All this is adding to the challenge of AMR. There is a need to deconstruct ‘One Health’ for having a better understanding of what needs to be done. Therefore, collaboration between different sectors is crucial for effective action on AMR.”

Sunita Narain
Director General, CSE
and Member, Global Leaders Group on AMR
FINANCING FOR ‘ONE HEALTH’ AMR ACTION PLAN IMPLEMENTATION IN LMICs
NATIONAL AMR ACTION PLANS ARE CRITICAL FOR LOCAL ACTION, BUT ARE IMPACTED BY DEPENDENCE ON DONOR FUNDS, WHICH NEED TO BE OPTIMISED

• AMR is a global challenge with different impacts at the local level based on local pathogens, type of resistance in those pathogens, and the social context. Context-specific solutions are, therefore, needed, which can happen through national AMR action plans.

• National Action Plan (NAP) implementation in many LMICs has been ineffective due to multiple reasons, with the key concern being lack of finances. Finances to support NAPs have been inadequate; currently, it is funded principally by donors or development partners. Donor and partner funds are aligned with the aims and objectives of their projects and focus on areas such as surveillance, infection prevention and control and antimicrobial stewardship — but they ignore awareness building, education and R&D, which are equally critical.

• Countries are looking for additional external funds. There is a need to find ways to optimise support and coordinate across and between donor priorities. Dedicated global investments are crucial and leveraging global health programmes can be useful through catalytic financing that can help initiate a foundational action or attract domestic funding. Existing and future mechanisms can consider financing key components of NAPs through milestone-based systems that can be tied to One Health key performance indicators. AMR needs to be effectively integrated into existing funding portfolios at the global level.

• Leveraging global health programmes can enhance adaptability and resilience. For example, models like SECURE led by the World Health Organization (WHO) and Global Antibiotic Research & Development Partnership (GARDP) could be considered more broadly. As AMR is a global problem that
is not just about stewardship but also about a socio-economic determinant of health, a global tax can be considered to push for funds to address key problems including those related to access.

DOMESTIC FUNDING MUST BE MOBILISED FOR SUSTAINABLE ACTION AGAINST AMR

• Domestic funding for AMR NAP implementation has been low. Governments in LMICs have competing priorities which makes action against AMR, a low priority. Besides, there are pressures and needs to invest on topical issues that can deliver the impact ‘now’. As a result, concerned ministries and departments do not get the required finances as well as mandate to act.

• Current financing is fragmented and inadequate to support various aspects. A dedicated budgetary support for a consolidated AMR programme from governments is considered critical for a targeted and coordinated action. In the absence of which, understanding on cumulative funds spent on AMR also remains diffused as different ministries or departments spend from their larger budgets. If such investments are well captured, it will further guide future goals and timelines.

• Ensuring long-term sustainability in funding can be achieved primarily through adequate domestic financing. AMR needs to become visible and get into budgetary framework of the country. This can happen through greater buy-in from political leaders and legislators. AMR agenda needs to be linked with national health plan or national health security and prioritised in national budgets. Governments also need to understand how AMR is making difference on broader economy, livelihood, food security, ecology in addition to health systems. Government buy-in will also create an opportunity for dialogue with stakeholders for stronger and swifter action on AMR.
**FINANCING FOR ONE HEALTH AMR ACTION PLAN IMPLEMENTATION IN LMICs**

- **Having a well-established national AMR coordination mechanism is critical for improving financing for NAP implementation.** By bringing all stakeholders together it can help understand available resources and gaps. Catalytic financing from global funding mechanism can help set up this committee, if needed. National and sectoral focal points of AMR should be able to understand all aspects of domestic fund mobilisation including budget systems/cycles and possible financing options in budgets across relevant ministries, departments and programmes.

- Measures adopted by LMICs to attract domestic funds include creating awareness particularly among top leaders, incorporating NAP activities in existing work plan and day-to-day activities of ministries/departments, using existing and new data to highlight the scale of problem, engaging with private sector and collaborating with neighboring countries such as on tech-support exchange visits.

- **NAP financing needs to be sustainable and not just depend solely on funds from the national governments.** Public private partnership is an opportunity to increase funding base and engaging with academia and civil society can help in optimization and utilization of resources.

- **Exploring innovative financing is essential for long-term support.** Options include strengthening health insurance programmes, integrating AMR cases in national medicines insurance, social impact bonds and micro-insurance mechanisms to complement existing resources.

**NATIONAL ACTION PLANS SHOULD BE COSTED, PRIORITISED, MULTI-SECTORAL YET INTEGRATED**

- A fully costed NAP enables different government ministries or departments to understand costs involved with activities assigned and enables their focal points to fit it into their budgeting cycles. **Cost-effectiveness of the plan that also**
leverages existing resources will help make a strong case. In addition to government budgets, costing will also help attract funds from donors, partners and private stakeholders and add to the long-term sustainability of financing.

• NAP in a way is a plan of many plans. It must be prioritized in LMICs as their governments will struggle to fund them completely. A costed and prioritized action plan is a sound basis for fund mobilization, resource allocation and short-and long-term action on the ground. Prioritization can be based on multiple factors including access needs, disease burden, low-hanging action with quick or high returns, existing capacities and ground realities and sectoral scenarios. Prioritisation will also make costing of NAPs easier.

• Multi-sectoral NAPs must be well integrated across concerned sectors, programmes and functions. Integration will make the case stronger and implementation effective. Containing AMR as a standalone programme will also be expensive and integration with other plans and sectors will create
opportunities for mainstreaming, co-financing and co-benefits. It can be similar to climate action plans, wherein funds available across sectors are used to meet the larger goal.

• Integration should include linkages with broader health systems, national health plans, national development programmes, universal health coverage, improving investments in water, sanitation and hygiene (WASH), biosecurity and immunization. For example, infection, prevention and control (IPC) should include AMR instead of a specific IPC for AMR. Successful integration also means that next generation NAPs involve One Health sectors from the beginning for greater buy-in from all sectors. Co-designing, co-development and co-implementation are important. AMR is everybody’s business. Financing will be benefitted by greater commitment, coordination, collaboration and presence of champions.

NATIONAL ACTION PLANS AND THEIR IMPLEMENTATION MECHANISMS SHOULD BE MADE FIT FOR PURPOSE

• AMR is not a disease and most issues in AMR are systems-based. It need not follow a disease vertical approach and become a vertical programme. The importance of how systems can be impacted needs to be considered and keeping the message simple is a key challenge. NAPs should avoid becoming too sophisticated and loaded with jargon.

• A ‘people-centered’ lens to NAP developments – though challenging and ambitious at this stage – should be used to the extent possible for gains in efficiency and effectiveness. While NAP implementation is government’s responsibility, NAP development should be far more consultative and less top-down as NAPs are instruments for behavior change. It will not just inform NAPs but also help create better mandate for change and political willingness.
Often led by health ministry, coordination among different ministries and departments responsible for NAP implementation has seen some concerns. **For effective One Health and multi-sectoral action, NAP coordination responsibilities should be housed at offices higher up than line ministries as happened during the Covid pandemic.** Depending upon the situation, the office of the President or the Prime Minister could be considered.

**Alternatively, a governance structure or a coordination mechanism that ensures multi-sectoral action can be formed.** For example, a coordinating body/entity established and mandated for interministerial coordination. Countries should examine a different coordination system so that it would enhance integration and some of the best practices such as to address climate change can be a big parallel for most governments.
FINANCING FOR ANTIBIOTIC R&D AND ACCESS IN LMICs
FINANCING FOR ANTIBIOTIC R&D 
AND ACCESS IN LMICs

PRIORITISATION OF INTERVENTIONS AND INVESTMENTS 
IN ANTIBIOTIC R&D SHOULD BE BASED ON PUBLIC HEALTH 
NEEDS, INCLUDING THOSE OF LMICs

• While conserving the antibiotics to keep them effective is most critical, but due to growing resistance against them, there is a clear need for new antibiotics. **It is important that public health needs should be central to interventions and investments for new antibiotics and making those available.**

• Antibiotic pipeline however is not sufficiently aligned with public health needs, specifically in LMICs. Most antibiotic R&D is informed by the priority pathogens listed by the WHO but there are no clinical assets against some of these, despite their disproportionate impact in LMICs. Besides, the public health burden in LMICs is extremely small for some of those under development. LMICs clearly have less tools to address the problem of resistance.

IMPROVING ACCESS MUST BE INTEGRAL TO ANTIBIOTIC 
INNOVATION FINANCING AND INTERVENTIONS

• Antibiotic access is a global concern. Part of the problem can be addressed through the antibiotic R&D and access connections, which have broken. Leave alone LMICs, most antibiotics developed over the last several years got introduced only in few out of many rich countries. This was largely due to the high cost of marketing and making them available but low expected returns either due to volumes, price or both. In addition, the northern richer countries are also facing stockouts as antibiotics are being withdrawn from their markets due to lack of profitability.

• **Bringing a newly developed antibiotic to LMICs is undoubtedly a greater challenge.** There are some initiatives to address this concern at an early stage. For example, CARB-X, a global non-profit partnership, includes antibiotic access and stewardship in contracts with early-stage antibiotic developers who in addition to funding, are also benefitted
by technical and marketing support provided. Similarly, the SECURE project, aims to ensure access of novel as well as old antibiotics to 100 plus countries including LMICs, which the small companies cannot do on their own. While these initiatives need to be encouraged, more such measures should be designed and promoted.

ACCESS TO OLD AND NEW ANTIBIOTICS REMAINS A BIG CONCERN IN LMICs WHICH MUST BE ADDRESSED SYSTEMATICALLY

- Access to right antibiotic at the right time is a key challenge in LMICs. While most antibiotics sold globally are off-patent, but they are not always accessible. They could be prior registered but not introduced in several countries due to commercial interests or regulatory burden. They could be also be inaccessible due to supply chain hurdles, procurement constraints, or affordability concerns.

- There are country-level examples wherein it became difficult to bulk procure an old antibiotic like co-trimoxazole for the needs of HIV patients. Similar concerns in the case of tuberculosis (TB), led to the formulation of Global Drug Facility which helps with access to low-cost tuberculosis treatments. Effective procurement mechanisms are therefore critical as procurement can act as a barrier despite the availability of generics. Equally important is to work with generic manufacturers and improve competition for low prices and better-quality antibiotics. Access to new antibiotics also needs to be linked with affordability to check the presence of substandard drugs as lack of affordability often drives cheaper and unlabeled drugs in the market.

- Antibiotic access should be supported with a foundational access to diagnostics and laboratory facilities. Equitable access to vaccines is also recognised to reduce antibiotic use and improve access. Based on the learnings from the Covid-pandemic response, Africa — in order to improve
equitable access to therapeutics, diagnostics and vaccines — is considering the need for strong national regulatory agencies (NRAs) and continental regulatory agency to help technology transfer, local manufacturing, shaping markets and pharmacovigilance.

**REGULATORY HARMONISATION IS NEEDED FOR EARLY ACCESS, BUT NEW ANTIBIOTICS SHOULD BE INTRODUCED IN A CONTROLLED WAY BY GOVERNMENTS**

- In addition to financial initiatives, non-financial measures and better coordination are the need of the hour. **Regulatory harmonization among countries cuts the cost to bring antibiotics to the market and can also expedite research and development.** By streamlining or minimizing data requirements, clinical trial needs and providing accelerated approval pathways, it can be a low-hanging outcome to improve access to both new and older antibiotics, particularly in LMICs. It can be more beneficial to the small-scale antibiotic developers with limited resources.

- Fast-track approvals can help early access, but a new antibiotic must be introduced into the healthcare system in a controlled way to avoid its over prescription in the private healthcare set up which may also not be adequately supported by laboratories. For example, bedaquiline, a drug for multi-drug resistant TB is available in India only as part of the government programme.

**FINANCING MECHANISMS NEED TO GO BEYOND PUSH-AND-PULL AND REFLECT A BALANCE IN PUBLIC-PRIVATE PARTNERSHIP**

- Push funding is helping build the pipeline at the early stages. Pull incentives are being tested in few countries, awaited in others and the impact on antibiotic R&D pipeline remains to be seen. The need to think beyond push and pull financing mechanisms is recognised. **Some form of global tax — like tax to an airline ticket — can be explored.**
Pharmaceutical companies have committed limited funds to fill the gap through the AMR Action Fund and are expected to do more. The industry has expressed the need for an end-to-end economic system for a sustainable antibiotic R&D ecosystem supported more so from the high-income countries.

Efforts in antibiotic R&D need to be reoriented to prioritise public health outcomes over volume sold and profits made. Governments and stakeholders should come together for greater coordination, prioritisation and collaboration.

GLG RECOMMENDATIONS TO ADDRESS THE ANTIBIOTIC PIPELINE AND ACCESS CRISIS IN HUMAN HEALTH

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 target product profiles.

2. Public and private funders should increase funding for push incentives to support the development of antibiotics and diagnostics.

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.

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 (WHO maturity level 3).

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

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

• Antibiotic development need not be taken up solely by the governments and the financing should not just be about bringing back the big pharmaceutical sector into antibiotic development. Instead, it should help small- and medium-scale developers who have taken up the responsibility. It is critical to invest and adopt measures that can help retain the expertise and talent involved in developing antibiotics. Financing must not depend on whether antibiotics are considered a ‘global public good’ or otherwise.

• In the case of LMICs, consortiums can help pool designated funds which can then be used for effective projects. Effective synergies are possible. There is a need to look for coherence.
LMICs CAN BECOME THE FIRST CHOICE AS A HUB FOR ANTIBIOTIC DEVELOPMENT

• The existing model of spending too much to develop antibiotics in rich countries and then introducing them to LMICs is broken. The revenues cannot match the heavy investments. This approach has not sufficiently helped the antibiotic pipeline and access in rich countries and LMICs. But scenario in LMICs can prove to be an advantage. **Tough bugs, high patient load, low cost of development and manufacturing can help LMICs become part of the solution.** Besides, antibiotics that will work in LMICs may also work in rich countries.

• Small antibiotic developers can fail more on chemical manufacturing controls (CMCs) and not on innovation. If companies good at CMCs like many in India and South Africa, are supported with subsidies and incentives linked to production, they can complement the growing number of innovative small companies to make a robust low-cost antibiotic development ecosystem in LMICs.

• Further, **as the cost incurred would be less, the expected low returns will not act as a big barrier.** This can help reduce innovation exits, overcome market failure in LMICs and antibiotics can then also enter into rich countries. LMICs can become an antibiotic development hub, at least for those required badly by them.

• No one country can be expected to own all pieces of solution to the problem. It is also impossible to have a strong intervention without investing in clinical trials in LMICs. Besides, **epidemiology should drive where studies take place and systems and incentives should be aligned to this.**
FOOD SYSTEMS TRANSFORMATION: THE ‘PREVENTIVE APPROACH’ TO SUSTAINABILITY
ANTIBIOTIC REDUCTION IS POSSIBLE IN INTENSIVE FOOD-ANIMAL PRODUCTION SYSTEMS THROUGH PREVENTIVE MEASURES AND ALTERNATIVES

- The European Union (EU) and United Kingdom (UK) have seen reductions in antibiotic use (>50 per cent) through better data collection on farm antibiotic use, increased motivation of farmers, setting targets for farm antibiotic use reduction, voluntary industry policies to routine farm antibiotic use, assurance schemes, as well as through a new legislation (in EU and UK) to ban routine farm antibiotic use in 2022 and 2024 respectively.

- There are examples from LMICs to show that antibiotic use reduction is possible in food-animal production systems through preventive measures. In Indonesia, a project involving breaking up a poultry farm into three biosecurity zones has shown up to a 40 per cent reduction in antibiotic use and nine per cent drop in the infection rates. Subsequent certification of their products from the ministry of agriculture also helps provide access to better price, market and livelihood for farmers. Nigeria is also conducting training of trainers, farmer trainings and farmer-field schools on measures like biosecurity, use of alternatives to keep diseases out of farms and reduce need for antibiotics.

- The Indian National Dairy Development Board (NDDB) has shown how use of low-cost ethnoveterinary medicines as alternatives to antibiotics has successfully treated mastitis and few other diseases in Indian dairy sector and brought down antibiotic use. The holistic approach helped farmers bring down their dependence on veterinarians, save cost of treatment, reduced productivity losses, and ensured safe food for consumers among other benefits from the win-win situation created.

- India’s Jubilant Foodworks Limited (JFL), a fast-food company, claims to have substantially reduced antibiotic
use in its poultry meat supply chain over the last 7-8 years. Starting 2017, in three-phased policy and implementation, JFL by 2024 claims to have reached a stage of no antibiotic use in poultry meat sourced from its four key suppliers. Possible through the use of alternatives and biosecurity and coupled with testing, supervision, audits, training and monitoring, it faced only 1-2 per cent higher mortality and 7-8 per cent hike in cost. JFL claims to have managed it because of large scale of its operations.

• Vaccination can also help reduce antibiotic use and be a part of this package depending upon local context, species, sectors. However, there are concerns specifically in LMICs about the high cost of vaccination compared to use of antibiotics, need
FOOD SYSTEMS TRANSFORMATION: THE ‘PREVENTIVE APPROACH’ TO SUSTAINABILITY

Experts listening to deliberations during the workshop

Experts discussing food systems transformation through a preventive approach

Experts listening to deliberations during the workshop
for maintenance of cold chain, limited availability of bacterial vaccines. Besides, farmers are often inadequately trained on vaccine administration and lack incentives for their use. **Vaccination need not be seen as the only solution when it comes to preventing diseases.**

**PREVENTIVE SOLUTIONS WILL MAKE FOOD SYSTEMS SUSTAINABLE AND SHOULD BE COST-EFFECTIVE OR INCENTIVISED TO BE UPSCALED**

- **Reducing occurrence of disease and the need for antibiotics through preventive solutions is the key.** Upscaling those will be critical and should be central to policy and interventions. While better animal health, adoption of the right biosecurity measures, appropriate hygiene and sanitation, and vaccination can reduce the need but use of alternatives can reduce the need as well as substitute antibiotic use. **Prevention should be**...
at the core of sustainable transformation of food systems. The RENOFARM project of the Food and Agriculture Organization of the United Nations (FAO) aims to transform sustainable agrifood systems by reducing need for antimicrobials.

• Greater reductions in antibiotic use are possible, if food-animal production moves away from intensive approach, which involves factors like high stocking density, poor nutrition, lack of animal care, high stress levels, poor hygiene, breeds for productivity but not disease resilience. For example, there is evidence that better animal care, later weaning in pigs can lead to massive reductions in antibiotics.

• Upscaling preventive measures will require them to be cost-effective or their adoption has to be incentivised. This will keep the cost of producing sustainably low and demand for such food intact. The balance currently is however tilted towards antibiotics which are often cheap. There are livelihood concerns of farmers and subsidies, insurance, remunerative pricing could be used to drive change and match their economic expectations. In the case of large integrated farming that is dependent on antibiotics, disincentives can work such as through consumer campaigns or regulations.

FOOD SYSTEMS NEED TO BE TRANSFORMED HOLISTICALLY AND MADE SUSTAINABLE

• While food and agri-systems can potentially be the core of narrative to contain AMR, the transformation of food systems must not be seen in isolation from the point of view of AMR. It should also be integrated with the needs to address climate change and biodiversity loss. **Food systems are at the intersection of this triple planetary crises and if addressed right will have multiple co-benefits.** For example, resilient indigenous cattle breeds not only help reduce antibiotic use but also reduce methane emissions.
• People and livelihood should be at the centre of the transformation process. It is only then the narrative will change in favour of sustainability and conversations focusing on money will shift. People should drive action and it is crucial to involve them.

• Challenges that need to be addressed on way to successful transformation include scaling up of preventive solutions, reducing the cost of producing sustainably and ensuring food security concerns while transformation.
MANAGING ANTIBIOTIC POLLUTION FROM MANUFACTURING AND THE ‘ACCESS’ LENS
GROWING GLOBAL MOMENTUM TO CURB ANTIBIOTIC POLLUTION FROM MANUFACTURING IS LEADING TO GOVERNMENT AND INDUSTRY ACTION THAT NEEDS TO BE STRENGTHENED AND EXPANDED

• At the global level, the momentum to contain antibiotic pollution from manufacturing is growing and guidance and standards related to managing antibiotic pollution from manufacturing are being developed. In the absence of which, there is a need for responsible manufacturing at the local level.

• The AMR Industry Alliance has taken certain measures in this direction, which includes risk assessments based on predicted no effect concentration (PNECs) and setting up and complying with discharge targets. Members of the industry alliance are expected to follow. While some big antibiotic manufacturing companies - irrespective of their membership status with the industry alliance - are known to monitor antibiotic residue levels in their own discharges and those of their suppliers, there are concerns related to transparency and availability of data in the public domain. Big companies typically have the means and resources and can support smaller companies across their supply chain in such monitoring.

• The criteria for procurement of antibiotics are also evolving. For example, Sweden is developing an environmental premium for those manufacturing responsibly and are able to meet antibiotic residue levels in effluents below a certain limit. It is focused on generics and includes certain antibiotics in national pharmaceutical benefits systems. The 'Antibiotic Smart Sweden' project considers a whole-of-society approach to address AMR that includes stakeholders like wastewater plants.

• The Regulatory Agencies Global Network against AMR (RAGNA) is working on a call to action which emphasizes
that registration of antibiotics should take into consideration factors like environmental protection among others.

- **In India, attention to address antibiotic pollution from manufacturing is growing.** There are examples of big companies claiming to use Zero Liquid Discharge (ZLD) approach and other high-end technologies, but small-and medium-scale antibiotic manufacturers rely largely on Common Effluent Treatment Plants (CETPs), which are being upgraded to treat antibiotics in manufacturing effluents in certain hubs across states. At the government level, there are guidelines issued by the central pollution regulator on monitoring Active Pharmaceutical Ingredient (API) residues while the issue of notifying and enforcing discharge limits for antibiotics is sub-judice at the highest level in the country.
Regulators in certain states with hubs are also cognizant of the need for necessary controls and checks.

- Just like in other parts of the world, regulations related to antibiotics in manufacturing discharge are weak in African countries despite a growing manufacturing sector and reports - though sporadic - of antibiotic residues in manufacturing wastewater. On one hand, there is need felt for a step-wise approach to keep the antibiotic manufacturing industry stay in business and on the other, there is a demand that the industry should be tasked with cleaning their wastewater and levied a 'sin-tax' based on the 'polluter pays' principle. In parallel, it is considered important that legislations to monitor antibiotic residues in manufacturing effluents are introduced and local manufacturing in Africa is scaled up.

**COMPLIANCE TO DISCHARGE LIMITS IS RESOURCE-INTENSIVE AND NEEDS TO BE APPROACHED SYSTEMATICALLY TO AVOID THE ‘ACCESS’ CRISIS**

- **Process control measures can cost-effectively minimize entry of antibiotics into the discharges** and complement resource and cost-intensive effluent treatment approaches. Manufacturers must be made aware, pushed and audited for leveraging these critical preventive measures.

- **Standards for monitoring antibiotic residue levels in manufacturing effluents are critical but it is important to be cognizant about the cost of mitigation and compliance to such discharge limits.** Implementation of these should avoid risks of jeopardizing access to antibiotics, particularly in countries of the global south with limited capacities to buy antibiotics but are in severe need of those. There could be options to adopt a step-wise approach that does not push manufacturers out of the business or risks transferring the cost of compliance to the consumers.
There is a need for global subsidies or incentives to clean up and support to control antibiotic pollution in LMICs in view of the fact that antibiotics are supplied to high-income countries at the cost of local pollution and resistance developed at the local level can spread across the globe.
TARGET SETTING: DIFFERENTIAL TARGETS FOR LMICs — ENABLERS AND CHALLENGES
TARGETS ARE NEEDED AND SHOULD BE DIFFERENTIAL FOR COUNTRIES. LMICs MUST UNITE TO PRIORITISE PREVENTION INTERVENTIONS FOR GREATEST IMPACT ON MITIGATING AMR

• Targets are a cornerstone in managing AMR as a global commons issue. Targets are needed whether they end up in the UNGA political declaration or not. These serve like an indication on whether to move forward or not and can inspire and trigger a momentum towards action at the country level.

• Some convergence is observed in different targets that are emerging such as related to unifying global targets,

Experts discussing targets for consideration at the High-Level Meeting on AMR
identification of ‘north-star’ target, targets on reduction in global mortality, reduction in human and animal antibiotic use, linking targets to Sustainable Development Goals (SDGs). Whichever targets are agreed on, they are the start not the end, meaning that an iterative process as in the case of climate change is needed.

- Targets should be differential for countries based on local context to help them, particularly the LMICs, make the right investments to achieve these targets. They should be equitable, ambitious yet practical and impactful, which apart from being technical is also backed by politicians and people. Numeric targets should be SMART (Specific, Measurable, Achievable, Relevant, and Time-Bound). Focus on global
financing, such as having a pooled resource can also be considered for achieving these targets.

- Prevention could be the key to achieving most of the targets. Such prevention interventions however depend on increasing access to the tools that are needed – existing access to antibiotics, vaccines, WASH, and IPC elements in healthcare settings. LMICs must unite on prioritisation of prevention interventions such as for achieving key SDG targets in order to have the greatest impact on mitigating AMR.

- Effective communication and messaging for politicians and policymakers around the targets is critical. For example, politicians would understand the language of the number of lives saved as it would mean more electoral votes and less push back. They can also be made aware of the added advantages of savings in economic cost if targets are
achieved. It is about a package of goods which can be of interest to governments based on economic analyses, returns on investments, social sciences and behavior change aspects.

• **LMICs NEED TO IDENTIFY ENABLERS AND CHALLENGES AND BUILD ON THEM TO MEET THE TARGETS**

There is a need to identify enablers and challenges for achieving the agreed-upon targets. This is more pertinent for LMICs in view of their priorities, challenges and resources available. Enablers and challenges have been identified in view of the proposed GLG targets but will also be useful for other similar set of targets.\(^3\) (see *Tables 1, 2 and 3*).

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3. Two groups of experts identified enablers and challenges across GLG proposed targets. Unique points from both groups are clubbed into different themes and overlaps excluded. For the two targets on antimicrobial use in agri-food systems, output is presented as one due to similar points.
Table 1: Enablers and challenges to achieve target related to deaths caused by bacterial AMR

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Prevention</th>
<th>Access to antibiotics</th>
<th>Antibiotic use</th>
<th>Health systems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccination of children and adults against infectious diseases</td>
<td>Ensuring access to effective quality assured antibiotics</td>
<td>Optimising antibiotic use at all levels</td>
<td>Strengthening health systems to manage access to affordable and quality care; leveraging health insurance; decentralisation of management and treatment with access category antibiotics</td>
</tr>
<tr>
<td></td>
<td>• Strengthened IPC and WASH efforts</td>
<td>• Streamlining production, procurement, and supply of ‘access’ antibiotics to all populations</td>
<td>• Addressing substandard and falsified antimicrobials</td>
<td>• Universal health coverage</td>
</tr>
<tr>
<td></td>
<td>• Focus on maternal and neonatal deaths due to sepsis</td>
<td></td>
<td></td>
<td>• Group practice to improve patient care</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Reducing severe and acute malnutrition burden in pregnant women and children under five in high-burden settings</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Point-of-care (POC) testing for early diagnosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Infrastructure to enable ICD 11 (international classification of disease) implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Implementation of digital health</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surveillance</td>
<td>Generate baseline data on global deaths/infections due to resistant bacteria</td>
<td>• Build capability to identify deaths due to infection and AMR</td>
<td>• Health and economic impact of AMR for sustainable funding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Enhanced laboratory capacity at the community and secondary level</td>
<td>• Investment in expanded models of health systems</td>
<td></td>
</tr>
</tbody>
</table>

| Challenges       | Weak leadership and coordination across sectors                           | Limited global and government funding for AMR programme (including WASH, IPC, vaccination coverage) | Lack of or no availability of baseline data at country levels, including hot spots; data on deaths due to AMR | Inadequate or underutilized diagnostics; cost implications of ensuring access to essential diagnostics; limited availability of POC diagnostics at facility level |
|                  | • Access barriers to older antibiotics                                    |                                                                                      |                                                                                                  | • Access barriers to older antibiotics                                                              |
|                  | • Issues related to the availability and cost of newer therapeutics, vaccines and vaccine hesitancy |                                                                                      |                                                                                                  | • Issues related to the availability and cost of newer therapeutics, vaccines and vaccine hesitancy |
Table 2: Enablers and challenges to achieve target related to antibiotic stewardship and responsible use in humans

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Access to antibiotics</th>
<th>Access to healthcare</th>
<th>Antimicrobial use and stewardship</th>
<th>Education and awareness</th>
<th>Technology</th>
<th>Surveillance</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Uninterrupted availability and access to ‘Access’ antibiotics in health systems</td>
<td>• Strengthening universal health coverage</td>
<td>• Strengthening existing antimicrobial stewardship (AMS) approaches in healthcare facilities (HCF) through guidelines, functional AMS committees</td>
<td>• Promoting education and awareness for pre-service, providers and the public and private sector healthcare professionals</td>
<td>• Leveraging contemporary technologies such as artificial intelligence, machine learning, clinical decision support system to support prescribers</td>
<td>• Improved lab capacity for culture sensitivity</td>
<td>• Availability of substandard antibiotics</td>
</tr>
<tr>
<td></td>
<td>• Encourage local production of ‘access’ antibiotics</td>
<td>• Expanding access to healthcare through primary healthcare centres</td>
<td>• Developing context-specific AMS programs in HCFs across disciplines</td>
<td>• Involving social scientists and communities to support behaviour change through information, education and communication (IEC) efforts</td>
<td>• Leveraging digitisation to strengthen information management systems for antimicrobial use, consumption and resistance (e.g. by using AMC tool and point prevalence survey)</td>
<td>• Timely availability of affordable diagnostics to enable early diagnosis to guide patient management; adequate regional supplies</td>
<td>• Current marketing practices of pharma companies and market failure w.r.t. global supply of access antibiotics</td>
</tr>
<tr>
<td></td>
<td>• Strengthened drug regulatory authorities to support availability of ‘access’ antibiotics</td>
<td>• Making private sector services accessible to public</td>
<td>• Monitoring consumption of antibiotics</td>
<td></td>
<td>• Ensuring availability of quality antimicrobials</td>
<td></td>
<td>• Challenge in monitoring difficult to reach areas; weak health systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Optimising use of antibiotics by informal care providers</td>
<td></td>
<td>• Develop/update standard treatment guidelines linked to essential medicines list (EML) and hospital formulary and AWaRe guidance</td>
<td></td>
<td>• Inadequate data on antibiotic use or consumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Enforcing regulations on antibiotic sale</td>
<td></td>
<td>• Timely audits and feedback</td>
<td></td>
<td>• Digital health infrastructure in LMICs and accreditation</td>
</tr>
</tbody>
</table>
Table 3: Enablers and challenges to achieve target related to antibiotic use in agri-food systems

By 2030, reduce the quantity of antimicrobials used in the agri-food system globally by at least 30-50 per cent from the current level

By 2030, eliminate the use of medically important antimicrobials for human medicine in animals for non-veterinary medical purposes, or in crop production and agri-food systems for non-phytosanitary purposes

<table>
<thead>
<tr>
<th>Enablers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agri-food systems transformation</strong></td>
<td>• Enabling access to transition programs and subsidies to support transition from antibiotic use to sustainable farming approaches</td>
</tr>
</tbody>
</table>
| **Prevention** | • Focusing on prevention to improve animal care, reducing disease, need for antimicrobials  
• Providing access to antibiotic alternatives such as vaccination, EVMs; strengthening farm biosecurity and animal health systems; emphasis on good farm management practices like biosecurity, reduced farm stress, early diagnosis and treatment  
• Focusing on balanced nutrition, animal genetics during breeding for disease resistance  
• Timely availability and access to low-cost, affordable diagnostics and vaccines |
| **Incentives** | • Economic incentives for farmers (e.g., insurance support and production-linked incentives to farmers for antimicrobial-free produce)  
• Investments compensating for loss of flock  
• Disincentives through consumer pressure |
| **Education and awareness** | • Promoting education, awareness and training across all levels including farmers  
• Involving social scientists and communities to understand behaviour and support behaviour change through IEC  
• Consumer awareness about antimicrobials in food and food products  
• Increased market access of products enabled by consumer pressure  
• Qualified workforce |
| **Antimicrobial stewardship** | • Coordinated global harmonisation of production and use of medically important antimicrobials (MIAs)  
• Monitoring farm registration and consumption of antibiotics in farms (aligned with AWaRe and MIAs)  
• Regulation, inspection and monitoring, of feed companies  
• Strong legislation and enforcement of restrictions on antimicrobial use in agri-food systems  
• Regional regulation for availability of antimicrobials – regulatory harmonization across neighbouring countries  
• Address research-policy gap to inform policymakers for policy decisions to reduce or ban use of MIAs  
• Develop an Essential Veterinary Medicines list for farms and a matching system like the WHO AWaRe guidance (Vet AWaRe)  
• Develop/improve disease treatment/management guidelines (like Veterinary assist)  
• Policies to discourage use of antibiotics; mandatory regulation and enforcement  
• Tools to inform policy makers to reduce use of medically important antimicrobials  
• WOAH database of antimicrobial consumption as baseline can be considered |
Technology and support

- Leveraging contemporary technologies to support farmers and prescribers
- Leveraging digitisation to strengthen Information Management Systems for antimicrobial use, consumption and resistance
- Support through corporate social responsibility programmes

Challenges

- Inadequate baseline information on antimicrobial use and consumption
- Different patterns of antimicrobial use in food systems in different countries, variation even between small- and large-scale system
- Disaggregated farms and farmers leading to barriers in uptake of interventions
- Negative impact on farmers’ income if not incentivized appropriately
- Political commitment for managing vertically-transmitted diseases like salmonellosis
- Economic considerations of farmers
- Sector-specific financing
- Evidence of impact on food security
- Risk of AMR getting lost in One Health
- Oversight on different sectors by senior-most level policy makers
- Lack of urgency to consider AMR from animal routes as a priority

Timothy Jinks making an intervention during group work on enablers and challenges for targets
ANNEXURE
ANNEXURE

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With an aim to influence and sharpen the future global action against antimicrobial resistance (AMR) in view of challenges and possibilities in low- and middle-income countries (LMICs), this report highlights their priorities to inform the deliberations and outcome of upcoming High-Level Meeting (HLM) on AMR at the United Nations General Assembly, September 2024.

The report presents key takeaways of an international workshop with an extensive involvement of experts and stakeholders from African and Asian countries. The action points belong to critical areas like financing of national action plans, antibiotic R&D and access, food systems transformation through the preventive approach, managing antibiotic pollution from manufacturing. It also reflects on key enablers and challenges at the national level that would help meet targets set for global action.