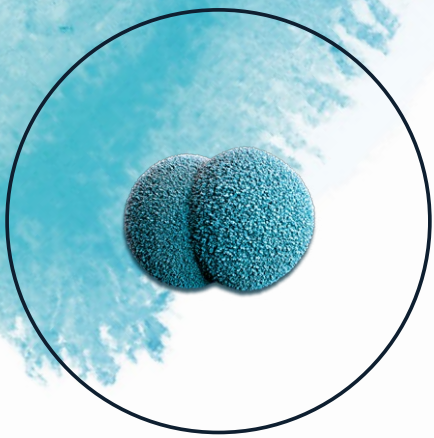

ACCESS TO ESSENTIAL
ANTIBIOTICS FOR INDIA:

CHALLENGES & OPPORTUNITIES

VIRTUAL BRAINSTORMING SESSION
23 FEBRUARY 2022

Global Antibiotic
Research & Development
Partnership

GARDP

ACCESS TO ESSENTIAL ANTIBIOTICS

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PARTICIPANTS

NAME	ORGANIZATION	DESIGNATION
NITI AYOG		
Prof. Vinod Paul	*NITI Aayog*	Member, Health
MINISTRY OF HEALTH		
Dr. Anuj Sharma	*WHO Representative on behalf of Lav Agarwal, Joint Secretary, MOHFW, GOI*	Technical Officer on AMR
Dr. Sunil Kumar	*DGHS*	Director General Health services, MOHFW, GOI
Dr. V.G. Somani	*DCGI*	Drug Controller General (India)
Mr A.K. Pradhan	*DCGI*	Joint Drug Controller (India)
Dr. Lata Kapoor	*NCDC*	Joint Director
INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)		
Dr. J. J. Cherian	*ICMR, New Delhi*	Scientist - 'E', Represented DG, ICMR
Dr. Kamini Walia	*ICMR, New Delhi*	Scientist
Prof. Subir Kumar Maulik	*ICMR, New Delhi*	Emeritus Scientist (Pharmacologist)
Prof. Amit Dinda	*ICMR*	Emeritus Scientist (Pathologist)
COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH (CSIR)		
Dr. Atya Kapley	*CSIR- NEERI*	Chief Scientist, Represented DG, CSIR and Secretary DSIR
Dr. D. Srinivas Reddy	*Central Drug Research Institute (CDRI) & Indian Institute of Integrative Medicine (IIIM)*	Director CDRI and Director IIIM
ALL INDIA OF MEDICAL SCIENCES (AIIMS)		
Dr. Randeep Guleria	*AIIMS NEW Delhi*	Director, Pulmonologist
Prof. N K Arora	*President AIIMS Patna*	Professor of Paediatrics, Member of National Task Force, COVID, Co-Chair -NTAGI
Prof. Shakti Gupta	*AIIMS Jammu*	Director, Hopsital Administration
Prof. Nitin Nagarkar	*AIIMS Raipur*	Director, ENT Surgeon
Prof. Debasis Biswas	*AIIMS Bhopal*	Dean Research & Prof. of Microbiology
Dr. Sagar Khadanga	*AIIMS Bhopal*	Head of Section of Infectious Diseases
Dr. Pooja Gupta	*AIIMS, New Delhi*	Additional Professor, Clinical Pharmacology
Dr. Biswa Mohan Padhy	*AIIMS, Bhubaneshwar*	Additional Professor, Pharmacology & Incharge Medical Procurement

NAME	ORGANIZATION	DESIGNATION
	WHO	
Ms Uhjin Kim	*WHO SEARO*	Technical Officer (EDM), Department of UHC
Maarten van der Heijden	*WHO Geneva*	Technical Officer, AMR Division
	GARDP INDIA ADVISORY GROUP	
Dr. Anand Anandkumar	*Bugworks*	Co-Founder & Chief Executive Officer
Dr. Harish Iyer	*BMGF*	Deputy Director, Digital and Health Innovation, Office of President, Global Health
Dr Shirshendu Mukherjee	*BIRAC, DBT*	Mission Director, Grand Challenges India
Dr. Camilla Rodrigues	*Hinduja Hospital, Mumbai*	Senior Consultant Microbiologist and Chair of the Infection Control Committee
	POLICY EXPERTS	
Dr. Vijay Chauthaiwale	*Policy Influencer*	Independent Healthcare Consultant
	EXPERTS	
Lt. Gen. (Dr.) Velu Nair	*Apollo Hospitals, Ahmedabad*	Formerly Profess or and HOD, Department of Internal Medicine, Armed Forces Medical College
Prof. Yatin Mehta	*Medanta Medicity, Gurgaon*	Head of Critical Care Medicine
Dr. BK Rao	*Sir Ganga Ram Hospital, New Delhi*	Chairman & Senior Consultant Dept. of Critical Care / Emergency Med.
Prof. Asit Mittal	*RNT Medical College, Udaipur*	HOD, Dermatology & Veneriology
Dr. Ruchi Nanavati	*PI-KEM Mumbai*	Professor & Head, Dept. of Neonatology
Dr. Kavitha Saravu	*PI-Kasturba Medical College, Manipal*	Professor & Head, Dept. of Infectious Diseases
Dr. Ayesha J. Sunavala	*PI-P.D. Hinduja, Mumbai*	Consultant, Infectious Diseases
	GARDP GENEVA	
Dr. Manica Balasegaram	*GARDP*	Executive Director
Dr. Subasree Srinivasan	*GARDP*	Medical Director
Dr. Jennifer Cohen	*GARDP*	Global Access Project Leader
Dr. Francois Franceschi	*GARDP*	Head Asset Evaluation & Dev/Lead SBI
Dr. Fernando Pascual	*GARDP*	Senior Access Manager
Dr. Yann Ferrisse	*GARDP*	Business Development Head
	GARDP SOUTH AFRICA	
Dr. Carol Ruffel	*GARDP/DNDi*	Head, South Africa
	GARDP DNDi INDIA	
Dr. Kavita Singh	*DNDi*	Director, South Asia
Raji Devarajan	*GARDP*	Clinical Research Manager
Prof. Y K Gupta	*GARDP*	Principal Advisor India strategy Dev.
Ms. Manisha Sharma	*DNDi*	Communication Head
Prakash Kumar Pathak	*GARDP*	Executive Assistant

EXECUTIVE SUMMARY

Antimicrobial resistance (AMR) is a major public health issue that has been identified as a high priority area by the Government of India. The One Health agenda recognizes the need for actors in sectors of human health, animal husbandry, veterinary medicine, agriculture and environmental regulation to coordinate efforts to mitigate AMR. Each sector in turn has multiple challenges which need to be addressed and monitored.

A virtual session, convened by GARDP, was held to discuss these key topics and was attended by 46 key stakeholders from public and private sectors with leadership roles in policymaking and regulation, basic science and translational research/ academia, medical practice, microbiology and diagnostic labs, and drug research and development in India. The aim of this session was to understand the existing mechanisms and structures in place in India and outline steps necessary to guide policy and framework that could enable **acceleration of access to essential antibiotics**.

This specific meeting discussed the AMR challenges related to human health such as the inappropriate use of antibiotics, lack of effective diagnostics, poor infection control measures, lack of stewardship programmes at all healthcare facilities, lack of access to essential and quality antibiotics and challenges of development and introduction of new antibiotics in India.

FIVE KEY THEMATIC SOLUTIONS THAT ARE CRITICAL IN THE AMR BATTLE EMERGED DURING THE DISCUSSION

These key thematic solutions could be summarised as follows:

- Improved diagnostic infrastructure for universal, accurate and timely diagnosis of drug-resistant infections.
- Enhanced antimicrobial stewardship programmes at all levels of healthcare as a norm.
- Mechanisms to incentivize local antibiotic drug development through innovation in clinical trials, streamlined and accelerated regulatory pathways and funding mechanisms, local and international. Additionally, mechanisms that will enable affordable procurement of novel antibiotics developed in high-income countries was also recommended.
- A legal and ethical framework for antibiotic prescribing and mechanisms for regular audits.
- Expanded surveillance network to better understand AMR in India at all levels of healthcare.

The importance of having a sustainable policy and coordinated framework involving multi-ministry, multi-department stakeholders to address AMR, clearly identifying the immediate, short-term, mid-term, and long-term goals was repeatedly emphasized. The impact of AMR on human health, the environment and economic growth will be enormous if adequate measures are not taken urgently.

Rapid investment is needed for developing new treatments, as well as improved infection control measures and the optimized use of antibiotics to help protect against the threat of AMR. It was also understood that no single department or sector can deliver a solution. Multisectoral partnerships, national/international collaborations and a public–private collaborative approach are all important to address the enormous public health and economic impact of AMR.

There was consensus around development of an AMR roadmap for policymakers and other decision-makers that would identify key quality and performance indicators coupled with clear achievement milestones in the next 5 years.

GARDP is ideally placed to collaborate and coordinate with key stakeholders on relevant topics with a goal of developing this roadmap and providing solutions that will complement India's National Action Plan on AMR.

INTRODUCTION

The rise of antimicrobial resistance (AMR) is outpacing new drug research and development (R&D), causing an alarming increase in human morbidity and mortality. The current estimates of the actual burden of AMR are not considered accurate because of the lack of a robust global surveillance system. This has prompted several studies to attempt to better estimate the burden of bacterial infectious diseases, particularly those that have become resistant to common antibiotics.

According to the recently published Global Research on Antimicrobial Resistance (GRAM) study[1], nearly 1.3 million people died worldwide due to drug-resistant infections in 2019, more than HIV/AIDS or malaria. More precisely, this study:

- Confirmed AMR as a major global health threat, based on estimates for 204 countries and territories;
- Showed that the extent and pattern of AMR varies by region and within regions, thus necessitating customized solutions;
- Reported that the burden of AMR in terms of attributable deaths is high in the South Asian region at 21.5/100,000 population.

The present report captures the key recommendations that emerged from a multisectoral discussion on the current state of the AMR ecosystem in India. Topics that are further explored in this report include:

- The AMR situation in India, and some of the major gaps and key measures needed in the human health sector to implement the National Action Plan on AMR.
- The key barriers to both R&D and access to new antibiotics in India, and how relevant stakeholders can facilitate the introduction and appropriate use of antibiotics.
- Potential solutions that could help mitigate the burden of AMR through coordination of efforts by various actors in the different sectors impacting human and animal health, agriculture and environmental protection.

The virtual session was attended by 46 key leaders from various sectors, including the Ministry of Health & Family Welfare (MOH&FW), Govt of India, NITI Aayog, Directorate General of Health Services (DGHS), Indian Council of Medical Research (ICMR), Biotechnology Industry Research Assistance Council (BIRAC), Central Drugs Standards Control Organisation (CDSCO), World Health Organisation (WHO), Central Drug Research Institute (CDRI), Council of Scientific and Industrial Research (CSIR), All India Institute of Medical Sciences (AIIMS), and scientists and physicians from a number of leading academic institutions as well as industry.

[1] *Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Feb 12;399(10325):629-655.*

ANTIMICROBIAL RESISTANCE IN INDIA

AMR has been identified as a major health and economic issue that is both an existential and futuristic threat and is recognized as a high priority area by the Government of India.

In India, the situation is severe, requiring urgent solutions. ICMR estimated the crude mortality rate from infectious disease in India at 417/100,000 population. These estimates represent statistics for all types of infections (bacterial, fungal, viral). Further, data in India suggests that:

- 410,000 children aged 0–5 years old die from bacterial pneumonia annually, accounting for 25% of child deaths in India[2].
- The incidence of bacterial sepsis in neonates is 14.3%, accounting for 25% of child deaths in India. About two-thirds of these cases were from Gram-negative bacteria[3].

Data from ICMR's AMR research and surveillance network also suggests that there has been a gradual increase in resistance to pathogens:

- India has three pathogens showing rates of multidrug resistance (MDR) in over 80% of cases: E. coli, K. pneumoniae and A. baumannii. Almost all other countries only have one: A. baumannii.

25% OF CHILD DEATHS IN INDIA ARE CAUSED BY BACTERIAL PNEUMONIA ANNUALLY

- MDR rates for E. coli, K. pneumoniae and A. baumannii reach as high as 88%, 81%, and 85%, respectively.
- Not only are these rates of MDR in India higher than those in high-income countries, but they are also significantly higher than in other LMICs.
- The trends are even more alarming for opportunistic pathogens, such as Pseudomonas aeruginosa and Acinetobacter baumannii, as resistance has been observed for not only first and second line antibiotics, but also for last line antibiotics, such as colistin[4].

The AMR situation in India is a public health threat that can undermine current and future health and well-being of citizens and economic growth. India is well placed to be in a position of leadership to develop a model for AMR solutions for South Asia.

[2] *National Action Plan on Antimicrobial Resistance, Govt. of India, 2017.*
[3] *Agarwal Ramesh, Shankar Jeeva 2016. The Lancet Global Health, 4 (10).*
[4] *Antimicrobial Resistance Research and Surveillance Network, Indian Council of Medical Research, 2017–2020.*

ACCESS TO ANTIBIOTIC: FOCUS AREAS FOR INDIA

India has launched its first National Action Plan (NAP) on AMR (2017-2022) and is well underway in terms of implementation. However, significant gaps have been identified and will need prioritization in the next NAP.

The following four key areas in human health were identified as requiring further strategic discussions and solutions:

- **Enhanced diagnostic capabilities:** The early identification of disease pathogens is key to supporting the appropriate use of antibiotics and improving patient outcomes. Investments are required in diagnosis and testing with better microbiology lab facilities particularly at district hospitals as well as rapid development of at or near point of care molecular diagnostics. Investment in development of diagnostics and research identifying biomarkers for the early detection of multidrug resistance is important in the next step of implementation of the Indian research agenda. Similarly, diagnostic capabilities that can expand the current surveillance networks are needed to ensure monitoring of all levels of healthcare in India.

- **Antimicrobial Stewardship Programme (AMSP):** Strengthening antimicrobial stewardship to minimize the inappropriate use of antibiotics is crucial to containing AMR and sustainable access to effective antibiotics. This should cover primary, secondary and tertiary healthcare systems across the country. Also, the AMSP may cover all sectors, like human health, agriculture/horticulture, veterinary and the environment. AMSP guidelines have been developed by ICMR, but a plan for widespread adoption and enforcement through intersectoral collaborative policies is needed with defined milestones as indicators of successful programme implementation.

- **New antimicrobial research, innovation and regulatory facilitation:** A policy shift may be required for ensuring there is significant investment in the R&D of new antimicrobials, repurposed antibiotics, vaccines, cell-based solutions, mRNA-based technology, etc. Creating innovative study designs would be important to help conduct fast-paced clinical trials for the early introduction of new antibiotics. International funding and public-private initiatives may be leveraged to develop new antibiotics. The learnings from COVID-19 could be considered for accelerating the regulatory approval process of new antibiotics for drug-resistant bacterial infections.

- **Procurement models for new antibiotics:** Innovative models and policies are needed that could accelerate timely and affordable access to new antibiotics for public and private markets in India, such as through a pooled procurement and commitment for purchasing a guaranteed volume at an agreed price from innovators/manufacturers. Such innovative market models are necessary to encourage the introduction of novel antibiotics in India, which will greatly help in the fight against AMR. India has a great opportunity to pioneer the introduction of novel market models, which can then be applied across other LMIC regions with a high AMR burden.

KEY COMMENTS

1. ENHANCED DIAGNOSTIC CAPABILITIES

There is a need for highly sensitive, affordable, and cost-effective early detection/ diagnostics techniques at district level hospitals that currently lack good microbiology labs.

Blood culture and sensitivity testing facilities could be considered under the new IPHS (Indian Public Health Standards). The government may consider a programme to launch a specified number of laboratories across India in a time-bound manner.

Investment is needed in the development of molecular diagnostic techniques and for identifying the appropriate biomarkers for the early detection of multidrug resistance. ICMR, BIRAC and CSIR may support the development of rapid diagnostics techniques through collaboration and by funding such opportunities. Innovative start-ups in AMR diagnostics could be supported and promoted through the Department of Biotechnology or other Government of India initiatives. Regulatory pathways for validation of these diagnostics are needed.

2. ANTIMICROBIAL STEWARDSHIP PROGRAMS

Key comments that apply across the public and private healthcare sectors at primary, secondary and tertiary levels of healthcare:

- **Education and awareness:** Increasing education and awareness is essential in both the government and private healthcare sectors. Education and awareness could be provided to graduate doctors, postgraduates, general physicians, and the public on the importance of the appropriate use of antibiotics. The inclusion of AMS in the medical and pharmacy curricula is another important measure that could be considered.
- **Quality measures:** A strong implementation and monitoring plan must be part of all stewardship programmes with a goal of measuring performance indicators and clear milestones that indicate improvement.
- **Diagnostics:** Diagnostics are essential tools in implementation of antibiotic stewardship by optimizing antibiotic prescriptions for better patient outcomes as well as for containing AMR. Incorporating point of care diagnostics into clinical pathways of care could potentially alter behaviour around antibiotics overuse and inappropriate use.
- **Technology:** A technology-based legal ethical system (i.e., some AI application/software-based technology) for prescription audit could help ensure the appropriate use of antibiotics. A pilot could be designed and be conducted to validate the technology.
- **Regulation:** Legislation and regulations may be strengthened and widely implemented to optimize the use of antibiotics particularly in the One Health and manufacturing sectors.
- **Post-marketing surveillance:** innovative methods for supervised use.

Post-marketing surveillance through pharmacovigilance activities at the national, regional and district levels is critical to containing AMR and safeguarding public health.

The Pharmacovigilance Programme of India (PvPI), a flagship programme of the MOH&FW, has identified AMR as one of its strategic priorities. Further, the National Health Policy 2017 recommended expanding the scope of pharmacovigilance practices to include prescription audits and the evaluation of antibiotic usage in hospitals and communities. PvPI is playing a pivotal role in reporting, educating, training and motivating healthcare professionals and other stakeholders in reporting adverse drug reactions as well as in the rational use of antibiotics.

For instance, PvPI has collaborated with several key institutions, such as Nizam Institute of Medical Sciences, Hyderabad, National Institute for Research in Tuberculosis, Chennai, and National Accreditation Board for Hospitals, providing training and enhancing awareness to contain AMR and its consequences. This programme could be expanded and PvPI could partner with other healthcare institutions both in the public and private sectors to support better antibiotic stewardship of old and new agents.

3. NEW ANTIMICROBIAL INNOVATIONS & REGULATORY FACILITATION

Need for the indigenous development of new antibiotics: Many lessons were learned during the COVID-19 pandemic. One was how India worked well in a collaborative (intersectoral, inter-departmental) way to tackle the COVID-19 pandemic, and then to manufacture vaccines, drugs (repurposed), and diagnostics in a short period of time and under immense pressure.

- Likewise, a collaborative R&D approach is required to develop new drugs and diagnostics to address the issue of AMR. For example, there is a need to explore innovative study designs to conduct accelerated clinical trials to develop new antibiotics. Limited market approvals based on strong Phase 2 data can also be a consideration for accelerated pathways. A consortium of R&D organizations, both public and private entities, could be formed at a national/international level to achieve this objective. Clinical trial data from India could form a key basis for generating evidence from patients with drug-resistant bacterial infections, which could potentially help in regulatory harmonisation (between DCGI and FDA/EMA/SAHPRA etc)
- The Council of Scientific and Industrial Research (CSIR), a dynamic network of 37 national laboratories, may be leveraged along with other public and private organizations to develop new indigenous candidate drugs, and to translate these into effective therapies to address AMR.
- ICMR, CSIR and other government institutions could work with international partners, like GARDP and Wellcome Trust, to develop world class AMR clinical trial infrastructure, so that India is one of the 'go to' countries to perform AMR clinical trials.

- **Incentivising R&D and creating new business models for investment:** Significant investment in the R&D of new antimicrobials, repurposed antibiotics, vaccines, cell-based solutions, and mRNA-based technology is required. The pharmaceutical industry is seemingly reluctant to invest in new antibiotics due to the current economic model of AMR and its lower revenues. To incentivize more R&D, guaranteed procurement policies and regulatory changes that will reward innovation and indigenous technologies will need to be created urgently. A cohesive effort between various organizations requires a comprehensive framework to be in place to achieve an effective outcome in advancing R&D of antimicrobials and diagnostics.

- There is a need to liaise with/leverage global partners, such as CARB-X and GARDP, to develop and enable access to newer antibiotics, especially for the priority list of pathogens.

- **Regulatory facilitation:** Steps will be necessary for the early introduction of new molecules. There have been significant efforts from stringent regulatory authorities to incentivize streamlined development pathways for anti-infective or antimicrobial agents specifically for multidrug-resistant bacterial infections such as accelerated development pathways, like QIDP (Qualified Infectious Disease Product) and LPAD (Limited Population Pathway for Antibacterial and Antifungal Drugs), which would allow fast tracking clinical development programmes.

The 'New drugs and clinical trial rules' were introduced in 2019 to encourage the development of drugs, including antibiotics. In these rules, an attempt was made to create an ecosystem that supports fast track regulatory approval mechanisms and the conducting of clinical trials. CDSCO also established a public relations office for guiding the research and development of new drugs and related clinical trials. This type of initiative may need to be reinforced.

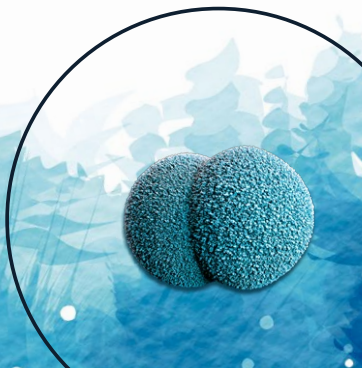
Learnings from COVID-19 regarding the accelerated regulatory approvals of drugs and diagnostics provides a promising future in this direction and may be leveraged. This will also feed into the global clinical data harmonisation narrative, where patient data from India will play an important role in global approvals, thus encouraging innovators from all over the world to consider India both as a clinical trials region and as a new market opportunity.

4. PROCUREMENT MODELS FOR NEW ANTIBIOTICS

New antibiotics are being developed against pathogens that are highly relevant to the Indian context, but antibiotic innovators across the globe are not incentivized to register and commercialize outside of high-income markets.

This has led to a situation of poor access to new antibiotics and is driving up the use of last line less effective and toxic antibiotics such as colistin. There is a need for solutions that could correct this imbalance in access to new antibiotics in India. New antibiotics that are being discovered anywhere in the world, need to be provided with access pathways, to make their entry into India possible and in sync with entries into high-income markets.

- **Market pull incentive:** The government could support the industry through implementing a pooled procurement strategy. There is a need for a guaranteed purchase volume/ guaranteed payment scheme, supported for example by public funding through advanced market commitments or subscription models to offer sales confidence to the pharma industry. A defined payment scheme of essential antibiotics negotiated by the government at a pre-specified price could ensure securing the antibiotics market and ultimately help make new antimicrobial agents available in a timely manner at an affordable cost. This approach would delink the return in R&D investment from the sales volume which is critical to sustainability of new antibiotics.
- **Centralized purchases:** A centralized purchase/procurement policy could be complemented by a centralized distribution system and a centralized quality control standard system. Such a centralized pool could feed the public health channels, whereas allowing innovators to directly sell into private markets, as long as stewardship frameworks are adhered to. Quality control measures for generic antibiotics may also be put in place. A reimbursement subsidy could be considered to enhance access and affordability.



SEVERAL OTHER KEY TOPICS WERE RAISED DURING THE BRAINSTORMING SESSION, COVERING THE FULL COMPLEXITY OF THE AMR LANDSCAPE.

- AMR surveillance: There is a need to collect information that represents all geographies and all districts in India, as well as to collect information from tertiary, secondary and primary centres, and to incorporate surveillance into the private sectors and down to the district level and beyond, taking this surveillance towards saturation.
- Environmental issues: How effluent is released and managed in the ecosystem is critical to the development of AMR. Antibiotics released in the wastewater from hospitals, solid waste, and dumped antibiotics contribute to generating AMR. It is therefore important that such hotspots are identified, and containment procedures implemented where possible.
- Law and prescription audits: With the introduction of newer antibiotics, strategies for their safe use in terms of guided prescription habits, monitoring, and audits (as implemented for opioid drugs) are required. Pharmacovigilance, including prescription audits inclusive of antibiotic usage, is critical in both the hospital and community settings. A One Health approach that coordinates AMR-related activities between various ministries, including the Ministry of Health and Family Welfare, Ministry of Environment and Forest, Ministry of Fisheries, Animal Husbandry and Dairying, and Ministry of Agriculture, would be required to formulate a comprehensive policy framework and a coherent governance model for the effective control of AMR. NITI Aayog can coordinate inter-ministerial or intersectoral collaboration in this area.

NEXT STEPS

AMR is a complex public health and development issue that will require a multi-pronged approach driven simultaneously by varied actors in a coordinated fashion. This will require a comprehensive roadmap for all three levels of the Indian healthcare system and across the One Health spectrum.

There is a need to consider formulating a policy and framework that is sustainable, comprehensive and complement the next version of the NAP on AMR, involving multi-ministry and multi-department input. A collaborative effort clearly identifying the immediate, short-term, mid-term and long-term goals is thus required.

There was a call by multiple sectors within the Indian government and the private sector for development of an AMR roadmap with identified focus areas as detailed below, that also marked key milestones needed to be achieved in the next 5 years for presentation to key policy-makers in India. A follow-up discussion session with a larger audience will be planned by the end of 2022.

Several meetings may be organized in 2022 with concerned stakeholders to hold dedicated discussions focusing on the below mentioned topics to build the roadmap for AMR solutions in India:

- **Innovation for therapeutics and diagnostics:** There is a need to bring together medicinal chemists, pharmacologists, and microbiologists in India on a single platform to develop a roadmap for the development of new antibiotics against priority resistant pathogens. There is also a need to synergize and strengthen the capacity for molecular diagnostics evaluation and the clinical trial ecosystem to accelerate both new antibiotics and diagnostics development in India.
- **Stewardship:** Guidance around best practices for implementation and monitoring of antibiotic stewardship will need to be developed for adoption across the health sector. This should be focused on delaying emergence of resistance to new antibiotics that are introduced into the market.
- **Regulatory facilitation:** Innovative and accelerated regulatory pathways that can enable early introduction of new antibiotics and diagnostics into the Indian market by supporting indigenous innovation are needed. This will require provision of regulatory guidance for antibiotic development and diagnostic validation, and adoption of best practices from across the globe. Data harmonisation is a real opportunity for India to become a preferred destination both for AMR clinical trials and as an early market to launch innovative antibacterials.
- **Procurement:** Brainstorming is needed on different models of regulated procurement and how to ensure affordability, as well as how to develop Indian leadership in the supply chain management of essential medicines.

AGENDA

Access to Essential Antibiotics: Challenges and Opportunities for India

A VIRTUAL BRAINSTORMING SESSION

23 February – 14.30 to 16.30 pn (IST)

Organised by: Global Antibiotics Research Development and Partnership (GARDP)

S. N°	TOPIC / SPEAKERS	TIME
	PART 1	
1	**Welcome & brainstorming session overview** Prof Yogendra Kumar Gupta – *Principal Advisor India Strategy Development, GARDP*	14.30–14.35 PM
2	**Antimicrobial resistance in India – a public health concern** Dr. Subasree Srinivasan – *Medical Director, GARDP*	14.35–14.45 PM
3	**Remarks** Dr. V.G. Somani – *Drug Controller General (India)* Dr. Randeep Guleria – *Director, AIIMS New Delhi* Dr. Sunil Kumar – *Director General Health services, MOHFW, GOI* Prof N K Arora – *President, INCLEN and President, AIIMS Patna* Dr. Vijay Chauthaiwale – *Independent Healthcare Consultant* Dr. Anuj Sharma – *WHO Representative on AMR (On Lav Agarwal)* Dr. J.J. Cherian Scientist – "E" – *(Representing DG, ICMR)* Dr. Atya Kapley – *Chief Scientist, NEERI, Representing DG, CSIR & Secretary DSIR*	14.45–15.00 PM
4	**Address** Prof V K Paul – *Member Health, NITI Aayog*	15.00–15.10 PM
5	**Activities of GARDP in India** Dr. Manica Balasegaram – *Executive Director, GARDP*	15.10–15.15 PM
	PART 2	
6	**Brainstorming session** **Moderator:** Prof Y K Gupta ***1. "Situation"** – What are the needs in India? (15min)	**2. "Barriers"** – How to facilitate the use of new antibiotics (15min)	**3. "Potential solutions"** – How to get new drugs available in India? What could be the role of policy makers on this context? (15min)* Dr. Lata Kapoor – *NCDC*	15.15–16.05 PM
	PART 3	
7	**Next steps** **Moderator:** Prof Y K Gupta	16.05–16.25 PM
8	**Closing remarks** Dr. Kavita Singh – *Director, DNDi South Asia*	16.05–16.25 PM

GARDP & SECURE

GARDP will continue to work on this topic and to initiate discussions with stakeholders on each of the recommendations around the policy and framework needed to enhance access to essential antibiotics.

As mentioned during the session, GARDP also is developing with WHO a new initiative to expand access to essential antibiotics, called SECURE:

- SECURE's mission is to help countries prepare for the silent pandemic of drug-resistant bacterial infections, and to give them access to a portfolio of essential antibiotics to meet local public health needs.
- SECURE's antibiotic portfolio will be adapted to countries' individual needs, providing both existing antibiotics that suffer from supply issues or are not widely available, and new Reserve antibiotics needed to treat resistant bacterial infections.
- SECURE will work with countries, local partners and implementers to strengthen antibiotic stewardship, update treatment guidelines, optimize use, improve surveillance and diagnostics, and collect real-world clinical data. SECURE will also contribute to generating data to further assess the efficacy of new antibiotics for the most threatening resistant infections, while giving special attention to vulnerable groups, like newborns, who carry an excessive share of the burden of AMR.
- SECURE will strengthen and enhance the sustainability of the antibiotic business model and expand the evidence base for the clinical utility of new antibiotics.

This initiative could be further discussed in the context of India.

CONTACT

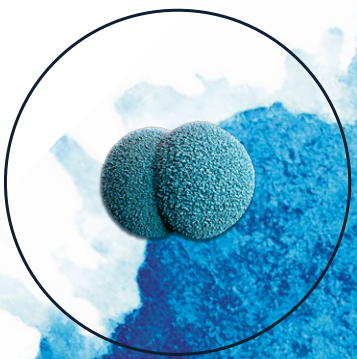
FOR MORE INFO

Global Antibiotic Research & Development Partnership (GARDP)

15 chemin Camille-Vidart – 1202 Geneva – Switzerland
contact@gardp.org – www.gardp.org

Drugs for Neglected Diseases initiative (DND*i*)

PHD House – 3rd Floor – 4/2 Siri Institutional Area – New Delhi 110016 – India



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