

LETTER TO EDITOR**Regulation, Innovation, and Stewardship: Pharmaceutical Policy Solutions for Antimicrobial Resistance in Pakistan****Muhammad Ali^{1*}****^{1*}Department of Pharmaceutics and Pharmacy Practice, Faculty of Pharmacy, Salim Habib University, Karachi, Sindh, Pakistan****Abstract**

One of the most critical public health issues in Pakistan is AMR. Rise in AMR is due to the presence of weak enforcement, limited pharmaceutical innovation, irrational antibiotic use and lacking of antimicrobial stewardship. Battling the AMR issue, a national action plan is present, but its implementation is a challenge that needs to be addressed and dealt with serious attitude. This letter emphasized the importance of regulation, innovation, and stewardship in shaping effective pharmaceutical policy responses to AMR in Pakistan. Industry-academia collaboration and “One Health concept”, along with stronger regulatory oversight, investment in research-driven pharmaceutical innovation, and nationwide stewardship initiatives, are essential for strengthening the healthcare sector.

Keywords: AMR, Innovation, Regulation, Antimicrobial Stewardship**Correspondence:****Dr. Muhammad Ali**

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Introduction

Antimicrobial resistance (AMR) is a public health emergency across Pakistan (1, 2). Antibiotics are dispensed in healthcare settings and pharmacies often without prescription adding to AMR rates, this requires strong regulation on pharmaceutical commercialization and adequate antimicrobial stewardship programs across whole Pakistan (3-5). This issue of AMR will make it difficult to treat infections. In Pakistan, the absence of policy is not the main issue. First national action plan on regulation of AMR in Pakistan was introduced in the year 2017 and updated as National Action Plan 2.0 (2024–2028), in this document it was make sure that the national priorities should be aligned according to the World Health Organization's (WHO) vision. Disconnected Implementation, lack of reliable and robust data are the real challenge for our policy makers (6-10). Irrational use of antibiotics in humans and veterinary is unchecked which is a main barrier in implementation of AMR policy (11). As far as pharmaceutical manufacturing is concerned, Pakistan is one of the largest pharmaceutical producers in South Asia. No or minimum innovation in antibiotic development and production is practiced. The market is bombarded by branded generics, particularly broad-spectrum "Watch group and reserve group" antibiotics that are frequently marketed and prescribed (12-15).

In current scenario this letter proposed that to avoid the disasters of AMR, regulation, innovation and stewardship should be seriously implemented and practiced across Pakistan as Pharmaceutical Policy Solutions.

Definitive and Upgraded Regulation

Firstly, it is need of the hour that regulation to be implemented should be definitive and technologically advanced. Regulatory infrastructure and reforms like Pharmacovigilance systems are improved after the establishment of The Drug Regulatory Authority of Pakistan (DRAP), in the year 2012 (16, 17). One of the main challenges in tackling of AMR is sale of antibiotics as over the counter (OTC) medicines regardless of legal restrictions, the cooperation between federal and provincial regulatory authorities remains unsatisfactory and fragile, which enhances the burden of AMR, this issue should be dealt seriously (18, 19). Pakistan needs a unified national AMR policy to be implemented which should contain the monitoring and oversight by e-prescription, strong pharmacy licensing, and mandatory recording of antibiotic sales and resistance patterns. WHO AWaRe classification should be adopted into hospital formularies and prescription guidelines throughout whole Pakistan (20-23).

Innovation and Antimicrobial Stewardship

Research-driven pharmaceutical innovation is the need of the hour for developing countries like Pakistan. The pharmaceutical industry of Pakistan has shown significant capacity of production, but due to import of active pharmaceutical ingredients and less investment in antibiotic research and development compromised long-term adaptability (24, 25). Research and development plays an important part in advancing healthcare outcomes and addressing health challenges (26). The government should encourage research and development by introducing tax credits, public-private partnerships, and a committed AMR innovation fund. Industry and academia should collaborate on research, innovation, and development. By this collaboration, priority should be given to antimicrobial innovation to ensure safety, efficacy, and better healthcare outcomes (27-30).

Antimicrobial stewardship must be made mandatory in healthcare and patient-oriented services. AMR is a cognitive issue. Policies should be revised and updated regarding antibiotic prescribing and marketing. Stewardship programs should be made mandatory in universities involved in medical, pharmaceutical, and health sciences education. Meanwhile, there is a dire need for public educational, pharmacist-led interventions and improved access to medication take-back programs to promote safer practices and reduce AMR risk (4, 31).

Pakistan needs a "One Health" Approach

The “One Health” approach should be adopted, recognizing the importance of human, animal, and environmental health. Misuse of antibiotics in poultry farming and livestock production contributes significantly to AMR. Agricultural antibiotic regulations should be integrated into Pakistan’s AMR policies for better outcomes (32-35). AMR threatens economic stability, medical tourism, surgical safety, and public confidence in healthcare systems. Increased hospitalization costs and prolonged illness affect low-income populations who already struggle to access quality care (36-38). At this critical moment, Pakistan can emerge as a regional leader by combating AMR. Strict enforcement and initiatives should be implemented to begin antimicrobial stewardship through national action plans (39, 40).

Conclusion

Pakistan’s healthcare system, economic stability, and future public health is threatened by AMR. National AMR action plans should be implemented and enforced to ensure better healthcare outcomes. Stronger pharmaceutical regulation, scientific innovation, and antimicrobial stewardship should be practiced at all healthcare sectors/levels. Industry and academia liaisons should be made for transformation in healthcare sector. The idea of “One Health” must be integrated into national policy to address AMR in humans and animals. Therefore, strict accountability and compliance is required against AMR.

Author Contribution

Muhammad Ali: sole author

Conflict of Interest

The author of the manuscript has no financial or non-financial conflict of interest in the subject matter or materials discussed in this manuscript.

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