

USP Commitment Statement

AMR Challenge Combatting Global Antimicrobial Resistance

Synopsis

Poor quality medicines are therapeutics that do not meet the quality specifications established for them and therefore do not have the intended benefit for patients, and may expose them to excess risk. Poor quality medicines may be substandard (i.e., inadvertently poorly manufactured, or degraded), or falsified (i.e., deliberately misrepresent their identity, composition, or source). In many cases, substandard medicines reflect poor adherence to quality standards and/or established best practices that protect the integrity of medicines across the supply chain. While the presence of poor quality antimicrobials are less common in countries with well-resourced regulatory systems such as the United States, a recent JAMA study indicated that 12.4% of antibiotics and 19.1% of anti-malarials are substandard or falsified in LMICs.¹ These drugs enable the development of pathogen resistance, which can spread to other countries, posing a global public health threat, including in countries with strong regulatory systems.

Poor quality medicines undercut the efficiency and effectiveness of all strategies aimed at addressing antimicrobial resistance. From stewardship of existing medicines, to ensuring access to medicines, quality is the foundation on which the strategies are built. For many places around the world, focusing on medication-use practices without adequate attention to the quality of medicines being used can waste scarce public health resources on poor quality antimicrobials that do not work or themselves drive resistance, undercut access to legitimate treatments, and result in unnecessary treatment escalation. With this in mind, ensuring medicine quality should be considered as an essential element of all AMR strategies, including stewardship programs. The quality of medicines cannot be assumed, it must be assured.

Adequately resourced regulatory systems and quality assurance programs, adherence to science-based international standards for quality and the collection of evidence to pinpoint weaknesses in the supply chain are essential to ensuring antimicrobial medicine quality.

USP is an independent scientific organization, founded in 1820, that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy, and capability building programs, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. Adherence to USP standards is required for medicines marketed in the US and USP standards are utilized in over 130 countries.

With two centuries of experience in the United States; decades of experience globally; over 1,000 staff and hundreds of experts from the scientific, healthcare practitioner and public health communities who volunteer their time on USP standard-setting committees; USP contributes quality standards, quality system strengthening, evidence generation, policy leadership, and coalition building to address the challenge of AMR globally.

¹ *Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries:*

A Systematic Review and Meta-analysis, **Journal of the American Medical Association**, JAMA Network Open. 2018;1(4):e181662. doi:10.1001/jamanetworkopen.2018.1662 August 10, 2018

USP's Commitment

Quality-assured medicines underpin all AMR strategies globally and they are essential to limiting the rise and geographic spread of antimicrobial resistance. Consistent with USP's mission to advance public health globally, USP commits to the following as a collaborative partner in the global effort to combat AMR:

1. **Develop and revise public, science-based quality standards for antimicrobial medicines.** USP will continue to develop new and revise existing USP quality standards for antimicrobial medicines to help enable manufacturers, regulators and other stakeholders to ensure the quality of antimicrobial medicines. To date, USP has developed over 690 monographs² and reference standards that support quality testing for antimicrobial drugs and their active pharmaceutical ingredients (APIs). (*Vaccines and Therapeutics*)
2. **Advocate for inclusion of medicine quality assurance in National Action Plans to combat AMR.** USP will expand its ongoing efforts to advocate for inclusion of policy on antimicrobial medicine quality in every country's National Action Plans to combat AMR. (*Vaccines and therapeutics; tracking and data*)
3. **Build awareness and foster a coalition for action on quality medicines.** USP will continue to play the leading role in the *Medicines We Can Trust* campaign launched in 2018. This multi-stakeholder initiative will raise awareness and build a coalition to advance policy and investment to ensure medicine quality. The link between poor quality medicines and AMR will be featured in this global effort. (*Vaccines and therapeutics*)
4. **Advance AMR discussions within the Asia Pacific Economic Cooperation (APEC) at the intersection of AMR and the trade of medical products.** Through USP's position as a Regulatory Center of Excellence within APEC, USP will further leverage this multilateral platform to foster dialogue on medicines quality and AMR, disseminate best practices, and engage stakeholders seeking to secure medical product supply chains across the Asia-Pacific region. (*Vaccines and therapeutics*)
5. **Generate evidence on the link between poor quality medicine and AMR.** USP is doubling research funded by USP through the USP *Quality Institute* to confirm the link between poor quality and AMR. Research projects led by fellows from Georgetown University and Boston University will investigate this link and their findings will be made public to help inform policy making and investment decisions. (*Tracking and data*)

The following are USP commitments and contributions through the USAID-funded, USP-implemented ***Promoting the Quality of Medicines (PQM)*** program:

6. **Strengthen quality systems to help regulators improve their ability to prevent, detect, and respond to the threat of poor quality antimicrobials.** USP will continue its work leading the USAID-funded and USP-implemented, ***Promoting the Quality of Medicines (PQM)*** program that strengthens regulatory and manufacturing capacity in developing countries to improve the supply of quality-assured medicines, including antimicrobial medicines. PQM has supported 28 national regulatory

² A drug monograph is a scientific document specifying standards for identity, purity, potency, and other attributes of a pharmaceutical product, ingredient, or preparation that applies across a medical product life cycle.

agencies to improve medicine quality surveillance and increase quality testing capacity in 80 laboratories. (*Vaccines and therapeutics*)

7. **Help pharmaceutical manufacturers of antimicrobials on the WHO Essential Medicines List become WHO pre-qualified as a provider of quality-assured medicines.** Through the USAID-funded and USP- implemented ***PQM*** program, USP will continue to work with manufacturers to expand access to quality-assured essential antimicrobials. The ***PQM*** program has helped 105 local manufacturers around the world improve the quality of their products, with over 13 antimicrobial APIs and products achieving WHO Prequalification and other regulatory body approvals in 2016-2017 alone. In addition to this work, USP implements numerous other donor-funded initiatives, partnering with governments, NGOs, and industry to strengthen quality-assurance systems to enhance access to affordable quality-assured medicines in LMICs. (*Vaccines and therapeutics*)

8. **Contribute to the ongoing global surveillance effort on the quality of antimicrobials.** Through the USAID-funded and USP-implemented, ***Promoting the Quality of Medicines (PQM)*** Program – we will continue to sustain a database - in collaboration with countries around the world - to collect data on the quality of medicines. This Medicines Quality Database (MQDB) has been a core surveillance resource used by WHO and other global authorities to research and report on the scope of poor quality antimicrobials and other essential medicines broadly. (*Tracking and data*)

As a partner in the global effort to combat AMR USP will collaborate with civil society, government, donor organizations and industry in executing these efforts.

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