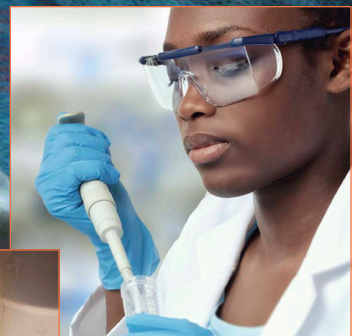

Advancing Quality of Medicines to Combat Antimicrobial Resistance



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Introduction

Antimicrobial resistance (AMR) presents a catastrophic risk to human health and life around the globe. The discovery and development of antimicrobials over the past century made it possible to treat once untreatable and deadly infections. However, the effectiveness of these medicines is now under threat from the increasing resistance of disease pathogens to antimicrobials. Some strains of bacteria can become resistant to multiple antibiotics and evolve into “superbugs” that can have devastating impact on the entire world. Unless there is an immediate, collaborative response at the global level, AMR could lead to 10 million deaths a year by 2050.¹

Key drivers of AMR include over-prescription of antibiotics, inadequate diagnostic testing, imperfect adherence to medication regimens, and rampant use of antibiotics in agricultural settings, where they are often used to promote animal growth rather than treat illness.² One underrecognized driver of AMR is poor-quality medicines—also referred to as substandard and falsified (SF) medicines—which can lead to treatment failure as well as escalate AMR. Substandard medicines are those that fail to meet standards or specifications of quality, while falsified

medicines deliberately or even fraudulently misrepresent their identity, composition, or source.³ A comprehensive analysis conducted in 2018 found that more than 12 percent of antibiotics circulating in low- and middle-income countries (LMICs) are SF medicines.⁴ The World Health Organization (WHO) estimates that, globally, \$30 billion dollars per year is wasted on medicines that do not work.⁵ This places pressure on resources in already distressed national health systems in LMICs and undermines efforts to deliver care to patients.

As an independent, nonprofit organization that works to improve global health through public standards and related programs, the U.S. Pharmacopeial Convention (USP) engages in global policy dialogue to advance medicines quality in AMR stewardship, supports advocacy on SF antimicrobials and other medicines through the #MedsWeCanTrust Campaign, facilitates evidence building through the USP Quality Institute, and supports implementation through the U.S. Agency for International Development (USAID)-funded and USP-led Promoting the Quality of Medicines Plus (PQM+) program. Pharmacopeial standards help manufacturers continue to make good-quality antibiotics and also provide a tool for countries to weed out poor-quality antibiotics from their markets.



Addressing medicines quality is critical to, and underpins, all AMR strategies—including stewardship, access, and research and development. This brief provides an overview of the state of the evidence on quality medicines and AMR and known gaps, discusses global and national efforts to bridge the divide, and suggests policy recommendations for country-level stakeholders leading strategies to address AMR to integrate considerations around medicines quality.

Making the Case: The Evidence

Evidence gathered over the last several years indicates that poor-quality medicines lead to AMR and contribute to the spread of infectious diseases. Poor-quality medicines can result from degradation through improper storage or distribution, or from poor manufacturing practices, either inadvertently or intentionally. The presence of poor-quality medicines drives AMR primarily through subtherapeutic dosing. When a patient takes a substandard antibiotic, bacteria are usually exposed to just enough levels of the active ingredient in the drug to kill weaker strains but strengthen pre-existing resistant strains and give rise to new ones.⁶ The same phenomenon is observed when patients do not adhere to the full treatment regimen. Resistant strains can grow and spread from human to human, leading to more virulent and deadlier infections. In this manner, SF medicines help accelerate AMR.

WHO has estimated that nearly 1 in 10 medicines circulating in LMICs are substandard or falsified.⁷ Antibiotics and antimalarials combined constitute 40 percent of SF medicines, making up the largest proportion reported to the WHO Global Surveillance and Monitoring System.⁸

Prior work on antimalarials has pointed to SF medicines as a cause of drug resistance⁹—especially in cases where patients receive poor-quality drugs on a consistent basis.¹⁰ One study conducted in 2013 across 39 countries estimated that consumption of poor-quality antimalarials was associated with 120,000 deaths among children under 5—about 4 percent of deaths in this age group.¹¹ More recent work modeling the impact of SF antimalarials showed that poor-quality antimalarials are responsible for over 12,000 child deaths and about \$890 million in costs.¹² The study simulated that if resistance to currently effective medicines develops, costs would go up by over 10 percent.¹³

One effort developed to understand the impact of poor-quality antimicrobial medicines in the emergence and spread of AMR was launched in 2016 by the USP Quality Institute, a research collaboration between USP and leading academic partners. Some of the research undertaken by the USP Quality Institute is looking at historical patterns of antimalarial drug resistance in southeast Asia and aims to help inform policy choices about treatment strategies in settings where it is known there are SF medicines. This work will also look at the poorly understood relationship between patient adherence and poor-quality medicines.

While the evidence base linking poor-quality medicines to AMR is more robust in the field of malaria, research to address other pathogens and drugs is emerging. For example, a low-quality version of rifampin, a broad-spectrum antibiotic often used as a first-line treatment against tuberculosis, can contribute greatly to the development of drug-resistant infections.¹⁴ The USP Quality Institute is currently looking at mechanisms of resistance to antibiotics.

Early findings appear to confirm prior assumptions that, when pathogens are exposed to subtherapeutic doses of SF medicines in vitro, their resistance can increase—which could then potentially give rise to the next deadly superbug. To further raise the stakes, pathogens exposed to SF antibiotics may not only become resistant to that one drug but to multiple other antibiotics as well. This specter of “pan-resistance” points to a greater need for diagnostic tools to screen for drug quality even before clinicians surveil patients for resistance.

Reduced private sector investment in research and development (R&D) for antibiotics also makes it more crucial to steward existing medicines while advocating for a stronger response to SF medicines and AMR. As resistance spreads, the expected lifespan of innovative antimicrobials is at risk, which is one of many factors driving the world’s major pharmaceutical companies to reduce or eliminate R&D investments on antibiotics and other antimicrobials. Companies may be deterred by the inability to recoup return or make a compelling case for investment relative to another therapeutic area.

New investments in generic manufacturing are also limited—for example, only four manufacturers worldwide continue to produce penicillin.¹⁵ Further, reforms to the regulatory pathways to take new innovations forward for the public good are limited, and there is a need to secure supply chains and strengthen post-market systems and quality-based procurement of drugs—mainly in LMICs—so as not to enable a market for SF antibiotics.

In light of escalating AMR, many countries also face a dual burden of both increasing resistance and rising prevalence of poor-quality medicines—scenarios that reinforce each other—making it more difficult and more costly to achieve improved health outcomes.

Shaping Frameworks for Global Action

A number of global stakeholders have begun to recognize the gap in addressing medicines quality in efforts to combat AMR. While there may be emerging evidence and signs that poor-quality medicines play a critical role in driving AMR, quality considerations and strategies have been lacking from global AMR dialogues and frameworks. Through a series of global stakeholder meetings and conversations, quality has slowly begun to enter the AMR agenda. Several key milestones have brought us to where we are to date.

The adoption of resolution 68.7 at the 68th World Health Assembly in 2015 was pivotal, as it endorsed the Global Action Plan on Antimicrobial Resistance and encouraged Member States to develop individual national action plans (NAPs) to fight AMR.¹⁶ At the United Nations General Assembly meeting in 2016, all 193 Member States committed to curb the threat of antibiotic resistance and called for more coordinated action, which led to the establishment of the UN Interagency Coordinating Group (IACG) on Antimicrobial Resistance in March 2017.



Many countries face a dual burden of both increasing resistance and rising prevalence of poor-quality medicines

As countries wrote their plans, global momentum among stakeholders to integrate quality into AMR followed. USP and other partners convened a side session at the Prince Mahidol Award Conference on emerging infectious diseases in January 2018 to catalyze action on medicines quality and AMR. Participants issued a call to action to recognize the link between poor-quality medicines and AMR and to develop, fund, and implement AMR NAPs. This call led to the May 2018 launch of the Medicines We Can Trust campaign, an initiative to build a broader coalition on the right to safe, quality medicines. The campaign now includes nearly 350 partners from over 40 countries. One of the campaign's key messages is to advocate for countries to monitor and survey their markets for SF antimicrobials. Conducting surveillance would provide countries with better evidence on the extent and magnitude of the problem, yield information about vulnerabilities in the regulatory system, enable regulators to take actions, and deter potential criminal activity.

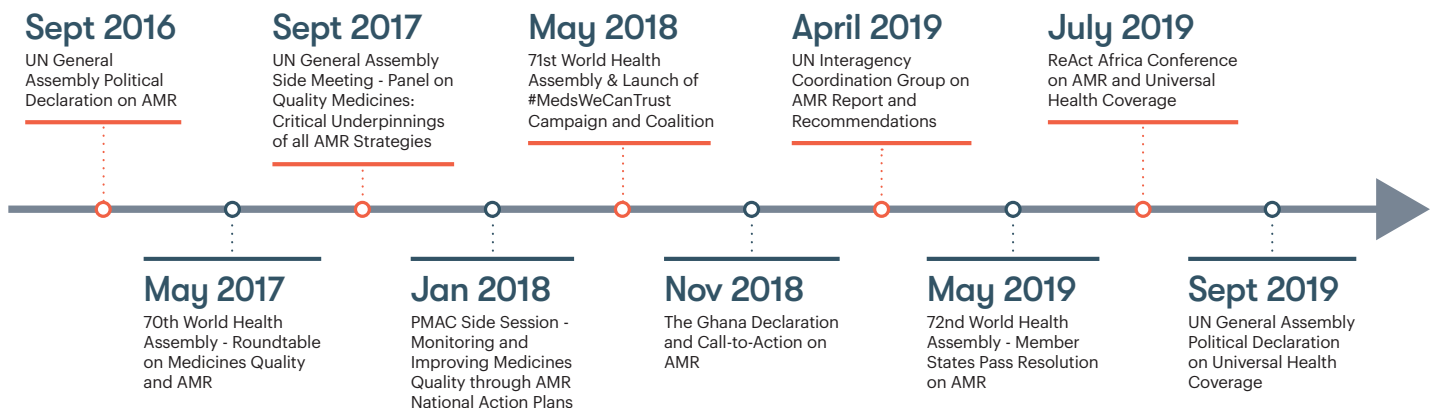
In November 2018, delegates from the governments of Ghana, Thailand, and the United Kingdom, along with representatives from the private sector, civil society, and WHO, the Food and Agriculture Organization of the United Nations, and the World Bank met and issued a call to action on AMR in the Ghana Declaration, which included a commitment to strengthening quality assurance and monitoring antimicrobials to minimize the impact of SF medicines.

The IACG on Antimicrobial Resistance released a set of recommendations in April 2019 pressing for urgent action to avert potentially disastrous consequences of AMR. In its final report, the IACG emphasized the importance of ensuring access to quality-assured antimicrobials, diagnostics, and vaccines as a part of strong health systems. Specifically, the IACG called for tackling SF medical products as a part of stewardship efforts, including strengthening national regulatory systems, improving AMR surveillance, and enhancing supply chains through implementation of track-

and-trace systems.¹⁷ The report also highlighted the need for efforts in universal health coverage (UHC) to promote both access to quality-assured medicines and appropriate use of antimicrobials in order to reduce AMR.¹⁸

These efforts culminated in a subsequent resolution on AMR, passed at the 72nd World Health Assembly in 2019. Introduced by the United States and negotiated among multiple Member States, the resolution intended to generate a renewed sense of urgency for coordinated and collaborative action on AMR. USP delivered a statement to support the resolution, urging for continued attention to medicines quality in AMR stewardship. The resolution called for increased surveillance of medicines quality and action to eliminate SF antimicrobials as well as enhanced regulatory oversight through health systems strengthening, technical assistance, and capacity building.¹⁹ In the same year, ReAct Africa held an important regional conference on AMR and UHC in Nairobi, Kenya, at which the USP Quality Institute discussed the role of medicines quality in AMR and led stakeholder dialogue on barriers and solutions to integrating quality into AMR NAPs and achieving UHC.

Additionally, the United Nations' political declaration on UHC, adopted by the General Assembly in 2019, prominently featured medicines quality in relation to medical product access as well as increasing awareness of SF medicines through strengthening legal and regulatory frameworks and capacity.²⁰ In conjunction with this meeting, the U.S. Centers for Disease Control and Prevention recognized commitments made by more than 300 partners, including USP, in its year-long AMR Challenge. In the journey to integrate medicines quality into efforts to fight AMR, USP, along with WHO, stakeholders, advocacy organizations, national ministries of health, donors, and others have worked to foster dialogue, share evidence, and galvanize momentum. Now that the global community has signaled the importance of weaving quality into AMR strategies, the next step is to facilitate implementation at the national level. ▲





Expanding the Reach to Countries

In 2015, WHO called upon Member States to develop AMR NAPs by 2017. In 2018, USP conducted a broad review of medicines quality in publicly available NAPs uploaded by countries to the WHO website to look at how medicines quality is integrated into AMR strategies. The plans were analyzed against both quality objectives in WHO’s Global Action Plan on Antimicrobial Resistance and WHO’s Prevent, Detect, and Respond (PDR) framework—the cornerstone strategy to address SF medical products. Strategies outlined in country AMR NAPs often include surveillance, research and development, and optimal antibiotic use, among others.²¹ Types of actions that fall under these categories are listed in the table below.

| Prevent | Detect | Respond |
|--|--|--|
| <ul style="list-style-type: none"> • Comprehensive legal framework • Multi-stakeholder engagement • Education and awareness • Supply chain integrity | <ul style="list-style-type: none"> • Access to laboratories and screening technologies • Risk-based inspection and surveillance • Reporting systems • Border control | <ul style="list-style-type: none"> • Alerts and recalls • Regulatory strengthening • Transparent legal process • Evidence-based policy and procedure |

Reference: World Health Organization. WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. 2017. <https://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>

Most WHO Member States did not have a NAP catalogued by WHO at the time of the analysis. Of the 41 NAPs analyzed, 27 mentioned medicines quality. Among these, 14 belonged to upper-middle and high-income countries and 13 belonged to lower- and lower-middle income countries. Some sample quality activities and goals mentioned in NAPs are listed below in the context of the PDR framework.

| Sample Quality Activities/Goals Mentioned within NAPs | |
|---|--|
| Prevent | <ul style="list-style-type: none"> • Good human and animal antimicrobial manufacturing practices • Coordination of quality control along the supply chain |
| Detect | <ul style="list-style-type: none"> • Establishment of a national surveillance system for antimicrobial quality • Strengthen laboratory and reporting systems |
| Respond | <ul style="list-style-type: none"> • Gradual implementation a single drug regulatory system across humans, animals, and aquaculture • Legislation to remove substandard medicines from markets • Enabling enforcement capacity of the drug regulatory authority enabling enforcement capacity |

The analysis identified a number of themes notable for their opportunities to capitalize about cross-country synergies.



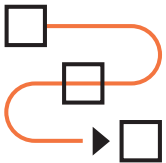
Surveillance for bacterial resistance and Medicines Quality

Recommendations included systematic and ongoing collection, analysis, and interpretation of data around antimicrobial medicines quality in antimicrobial resistance at both the national and local levels as well as the establishment of networks and strengthened post-marketing drug quality monitoring systems.



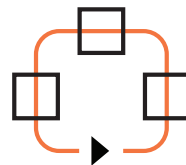
Apply One Health approach

Countries discussed strengthening coordination efforts by national regulatory agencies to support their capacity to enforce quality standards of antimicrobial drugs for veterinary, human, and aquaculture use. Increasingly, countries are starting to understand and address the connection between antimicrobial use among humans and animals.



Prevent S&F across the product life cycle

A number of countries included establishing quality management systems to manage the supply chain in SF medicines. Also mentioned was the need to ensure the quality of antimicrobials through good manufacturing practices.



Support systems to combat AMR threats

Some NAPs included plans for national systems to enhance access to and appropriate use of quality-assured, safe, effective essential antibiotics. A systems-level approach, including bolstering regulatory capacity, is needed to fight the threat of AMR and poor-quality medicines.

Since this analysis was conducted, more countries have developed NAPs.

According to WHO, 117 countries have completed plans, and 62 are in the process of doing so. As a result, USP plans to conduct a second-phase analysis of the additional NAPs to see how the global dialogue around the medicines quality issue has potentially influenced its inclusion in subsequent plans. This policy brief highlights the experiences of three countries—Indonesia, India, and South Africa—and their ongoing and planned activities to prevent, detect, and respond to medicines quality issues in their AMR strategies.¹

¹ Country snapshots were derived from presentations made at a side event, “Monitoring and Improving Medicines Quality through AMR National Action Plans,” alongside the Prince Mahidol Award Conference in January 2018.



Country Snapshot 1

Indonesia

INDONESIA is a diverse archipelago of 34 island provinces and over 260 million people, with a large and rising burden of AMR. Studies have found that 50 to 80 percent of antibiotic use at hospitals was inappropriate, either given without indication or prophylactically. Additional research conducted in 2013 discovered that AMR prevalence can reach up to 40 percent. Indonesia’s NAP on AMR tackles several medicines quality objectives. Under the Ministry of Health, the National Agency of Drug and Food Control (NA-DFC) manages antimicrobial stewardship.

| | |
|----------------|--|
| Prevent | <ul style="list-style-type: none"> • NA-DFC responsible for quality assurance of antimicrobial medicines. • Control of production facilities to ensure that pharmaceutical companies have met and fulfilled good manufacturing practice (GMP) requirements. • Supervision by NA-DFC of all stages of medicines production, including quality assurance, research implementation (clinical or bioequivalence test), medicine distribution monitoring, and pharmacovigilance. • Control of product and labeling information. |
| Detect | <ul style="list-style-type: none"> • Pre- and post-marketing surveillance, including routine GMP inspection of production facility to ensure se-curity, efficacy, and quality. • Assurance of good distribution practices. • Monitoring of good prescribing practices to ensure appropriate antibiotic prescribing and that no antibiotic is given to patients without prescription. • Sampling and testing. • Pharmacovigilance, which includes post-market monitoring on safety aspects. |
| Respond | <ul style="list-style-type: none"> • Control on labeling/product information |

Indonesia recognizes gaps in its NAP to address quality in AMR include sale and use of antimicrobials without a doctor or veterinarian prescription; use of antibiotics as animal growth promoters; dependence on the availability of combination drugs for tuberculosis not yet produced in Indonesia; and post-market supervision of antibiotics. In the future, Indonesia plans to require healthcare facilities to report data on antimicrobial use (including lack of efficacy) and to have a public campaign to address prescribing practices among health workers. ▲



Country Snapshot 2

India

THE INDIAN GOVERNMENT has implemented a number of provisions and steps to prevent, detect, and respond to antimicrobials of poor quality. Antimicrobial stewardship efforts in India have been championed at the highest levels, including by Prime Minister Narendra Modi. The Ministry of Health and Family Welfare has identified AMR as 1 of its top 10 priorities.

| | |
|----------------|--|
| Prevent | <ul style="list-style-type: none"> • Circular issued by Ministry of Agriculture to Commissioners of Animal Husbandry in all states advising veterinarians, feed manufacturers, and those involved in treatment of animals for judicious use as treatment of ailing food-producing animals and not as growth promoters. • Sensitization of State Drug Controllers at Drugs Consultative Committee meetings to take appropriate measures to prevent sale of antibiotics without prescription. • Efforts to control the sale of irrational and unlicensed fixed-dose combinations of antimicrobials. • Monthly awareness program conducted by the Pharmacovigilance Programme of India (PvPI) on antibiotic misuse, involving physicians, nurses, pharmacists, supply chain personnel, and community members. |
| Detect | <ul style="list-style-type: none"> • PvPI surveillance program implemented through 200+ monitoring centers at various centers and hospitals, including antibiotics use, adverse event reporting, and reporting cases of antibiotic resistance. • National Drug Survey to assess the extent of Spurious and Not of Standard Quality (NSQ) drugs in the country (conducted during 2014–2016). |
| Respond | <ul style="list-style-type: none"> • Efforts to control the sale of irrational and unlicensed fixed-dose combinations of antimicrobials. |

In India’s NAP on AMR, efforts to address quality are interwoven throughout the relevant goals and objectives. The central regulators will soon join the state regulators in activities to respond to the AMR threat, including inspecting manufacturing facilities to improve compliance with GMP in domestic manufacturing in India. ▲



Country Snapshot 3

South Africa

IN SOUTH AFRICA, medicines quality is incorporated under antimicrobial stewardship. Several legislative milestones around prevention of SF medicines have bolstered South Africa’s work in this area.

| | |
|----------------|--|
| Prevent | <ul style="list-style-type: none">• National Drug Policy of 1996 instituted to ensure medicines are tested for quality and safety.• Medicines and Related Substances Act created the medicines regulatory authority—the Medicines Control Council (MCC).• Implementation of a registration system allows for quality reviews and requires product registration before sale or distribution.• Inspectorate division licenses and inspects facilities for GMP compliance. |
| Detect | <ul style="list-style-type: none">• Product failures and adverse drug reactions are reported nationally and internationally.• Laboratory systems monitor quality assays and pharmacovigilance reporting systems. |
| Respond | <ul style="list-style-type: none">• MCC serves as a strong and well-established regulatory presence to respond to problems, and register and regulate human and animal medicines against quality and efficacy standards.• Law enforcement collaborates with Customs and Port Health for border control and inspection of imported medicines, with the power to seize SF products.• Recalls process communicates process failures that result in poor-quality medicines.• Medicines and Related Substances Act allows for reliance and harmonization with other regulators, such as participation in the Zazibona initiative, a collaboration among certain member states of the Southern African Development Community—a regional economic community—to pool resources to review dossiers collectively so more quality-assured products can enter the market. |

The healthcare financing system in South Africa influences the access and use of medicines. When funds are pooled to purchase medicines, they do not need to be purchased out of pocket. The absence of a market outside the system substantially reduces the opportunity to sell SF medicines. One of the key challenges in sourcing good-quality and safe medicines is inadequate capacity of national regulatory authorities. One way to address this is through capacity-building activities aimed at developing and improving the expertise and competence of evaluators.

While many countries have included quality in their national AMR strategies, many still have not. As LMICs transition from global to domestic procurement and manufacturing of medicines, they are challenged with securing medicines supply chains that may contain a mix of quality-assured, poor-quality, and unknown quality medicines.²² Medicines quality as an issue in AMR is also an increasing concern for developed countries, whose citizens are more and more likely to purchase medicines via the internet. In these cases, drug sources and quality may be unknown and not assured.

With the globalization of the supply chain, China and India have also become the world’s major manufacturers for ingredients used in pharmaceuticals. While many developed countries have robust plans to tackle AMR, most have not looked specifically at how to address quality. However, there are some exemplars. The United Kingdom, whose AMR national plan did not originally include quality as a focus area, has now incorporated medicines quality as an integral component of its strategy. The UK released a new five-year plan on AMR in 2019, which includes a subsection on better quality assurance of AMR health products.

Some barriers and potential solutions identified as part of global and regional conversations are included in the table below. As part of its work on AMR, the USP Quality Institute is conducting qualitative research to discern reasons why LMICs have not integrated quality into their NAPs and to provide policy tools for implementation of quality goals and objectives.

| Barrier | Potential solution(s) |
|--|--|
| Regulatory capacity at the national level | <ul style="list-style-type: none"> • Implement nationally and externally funded capacity-building initiatives |
| Political will and national champions | <ul style="list-style-type: none"> • Show evidence of public health and economic/fiscal impact • Raise media attention leading to public awareness |
| Engagement of public and private stakeholders | <ul style="list-style-type: none"> • Prioritize stakeholders • Engage in additional outreach to civil society, patient advocacy groups, etc. |
| Financial and technical resources | <ul style="list-style-type: none"> • Leverage existing national, regional, and global collaborations (e.g. Ecumenical Pharmaceutical Network in Africa) • Collaborate with other stakeholders involved in monitoring medicines quality |

As countries move toward implementation, resources such as country best practices, case studies, and other tools—as well as technical support—is needed to operationalize medicines quality objectives in the Global Action Plan and PDR framework. The WHO Toolkit for antimicrobial stewardship in healthcare facilities in LMICs addresses the need to ensure measures are in place to ensure continued access to quality-assured antibiotics, including government actions to prevent sale of SF medicines.²³ PQM (the predecessor to PQM+) has been working since 2009 to strengthen medicines quality surveillance systems in LMICs. PQM has supported regulatory authorities in identifying poor-quality medicines and taking enforcement actions, including product recall. In its second phase, PQM+ will continue to expand upon these efforts. ▲

Policy and Advocacy Recommendations

To advance efforts to implement strategies to address medicines quality and to fill the evidence and action gap, USP recommends:

Policy

1. Build evidence and awareness about the link between poor-quality medicines and antimicrobial resistance

Country health and finance ministries need more evidence about the impact of poor-quality medicines on public health and the return on investment for investing in quality medicines. Key actors working on AMR should continue to utilize existing and emerging evidence to urge decision-makers and policymakers to incorporate quality into NAPs and to allocate resources to implement these activities. National medicines regulatory agencies should be included in discussions around quality assurance and surveillance activities for AMR medicines.

2. Integrate strategies from WHO's "Prevent, Detect, Respond" Framework into NAPs.

Countries can include key elements of the WHO cornerstone framework on SF medicines into their AMR NAPs. This framework is flexible so that countries can tailor actions based on their needs, capacity, and resources. National and regional stakeholders may want to consider bringing together stakeholders to share suggestions for implementation, barriers, and solutions, as well as tools and resources to support implementation of PDR actions. Countries may also benefit with assistance in prioritization of these strategies.

3. Participate in and establish collaborations to share data at the regional and global levels.

Existing activities at the regional level and establishment of new collaborations can be leveraged to collect and share data, exchange lessons learned, and coordinate influence for dialogues with global organizations, including multilaterals and donor agencies. For example, countries can harmonize regional guidelines through multistakeholder, cross-country collaborations. The African Union, Asia-Pacific Economic Cooperation, WHO country and regional offices, and other regional bodies should be leveraged to help with activities to bolster quality management systems.

Advocacy

1. Develop guidance for healthcare and pharmacists to act on medicines quality issues.

Efforts to ensure quality medicines can be integrated into AMR stewardship efforts in a variety of settings where patients receive care, including hospitals, facilities, and clinics. Clinicians and pharmacists need knowledge and tools to identify poor-quality drugs, advise patients on reliable sources, report suspicious products, and make decisions on administering drugs to patients if their quality is poor or unknown. Those working in healthcare should have access to resources they can share with patients to inform them about poor-quality antibiotics. Countries should consider how they can include healthcare workers in dialogue on more upstream efforts, such as regulatory oversight and screening of antibiotics quality.

2. Provide educational resources for patients and consumers on poor-quality AMR medicines.

Patient and consumers need information for what to look for, how to report suspicious products, and knowledge to empower them to demand quality products. Patients should be encouraged to buy medicines from credible sources and only with a prescription from a healthcare worker. National consumer and advocacy groups can help contribute to and lead efforts to engage with patients, especially as #MedsWeCanTrust takes the campaign to countries in 2020.

3. Build and sustain political will at the national, regional, and global levels.

Country examples of progress show that national champions are critical in the fight against AMR, including the establishment of champions at the highest levels of country leadership and integration of grassroots voices to illustrate the human impact of policies to integrate quality into the fight against AMR. Countries should not only identify and establish key national champions to carry this issue forward but should also build a coalition of champions to sustain that political will.



Finally, USP urges national stakeholders to take stock of the One Health approach as a comprehensive way to address human, animal, and environmental health in the context of AMR and medicines quality.

Acknowledging the interconnection of human, animal, and environmental health, including the potential transmission of resistant bacterial strains between species, responsible use of quality-assured medicines in both animals and humans in line with the WHO-recommended One Health approach is essential to protecting overall public health and to ensuring the continued effectiveness of antimicrobials. A more holistic view is required to solve the AMR crisis.

Continuing to Invest in Antimicrobial Medicines Quality & Next Steps

There is an urgent need to continue to move the needle on the issue of quality medicines and AMR, particularly as efforts move from the global level to regions and countries. Without tackling quality, other efforts to achieve universal health coverage and strengthen regulatory systems may be seriously undermined. For AMR stewardship efforts to be effective, countries need to integrate medicines quality into their AMR national strategies and implement efforts to prevent, detect, and respond to poor-quality AMR medicines. The global community should also continue to provide financial and technical resources to countries to implement national AMR plans. USP continues to call for collaborative action on and investment in medicines quality in order to solve the global AMR crisis. ▲

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