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Potential activities to reduce the extent of substandard and falsified antibiotics across Africa and associated antimicrobial resistance

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Antimicrobial resistance (AMR) is a global public health threat exacerbated by inappropriate antibiotic use. This is particularly important in Africa. The availability of substandard and falsified antibiotics, particularly among African countries, contributes to this adding to the burden of AMR. Poor monitoring and regulatory controls among African countries increases the public health risks of these antibiotics. This is especially the case in the informal sector. Addressing Africa's battle against substandard and falsified antibiotics requires an integrated approach building on current WHO, Interpol and Pan-African initiatives. Activities include harmonizing regulatory activities across Africa and increasing the monitoring of available antibiotics as well as fines and sanctions for offenders. In addition, reducing the current high levels of inappropriate antibiotic use makes the market for falsified and substandard antibiotics considerably less attractive.

KEYWORDS

antibiotics, antimicrobial resistance, substandard antibiotics, falsified antibiotics, informal sector, policy initiatives, health authorities, sub-Saharan Africa

1 Introduction

Antimicrobial resistance (AMR) increases both morbidity and mortality as well as appreciably increases healthcare costs if not addressed (1–4). As a result, AMR is now considered a critical global public health threat and the next potential pandemic unless multiple activities are undertaken across countries to address this situation (5–7). The principal countries to target to reduce AMR are low- and middle-income countries (LMICs) since the burden of AMR is greatest among these countries, which includes African countries (8–10).

AMR is driven by high levels of inappropriate use of antibiotics (11–13). High levels of AMR among African countries are also enhanced by the considerable availability of substandard and falsified antibiotics (14–18). The economic burden of substandard and falsified medicines is considerable with an estimated US\$30.5 billion globally spent on these medicines each year alone (19, 20), which includes antibiotics (20). In addition to the appreciable monies spent on these medicines, Beargie et al. (2019) estimated that in the Northern Region of Nigeria alone, 9,700 deaths each year were due to substandard and falsified medicines with an estimated economic loss of \$698 million (\$697–\$700 million) (21).

In their study, Feeney et al. (2024) documented that antibiotics accounted for 36% of all counterfeit medicines seized globally by Customs (22). Similarly, Ozawa et al. (2018) ascertained that the overall prevalence of substandard medicines among LMICs was 13.6%, highest in Africa at 18.7% (23). Wada et al. (2022) also found that the African region had the highest prevalence of poor-quality medicines, which they estimated to be 18.7% of available medicines (14, 24). Similar rates were reported by Asrade Mekonnen et al. (2024), who estimated that the prevalence of substandard or falsified medicines across Africa was 22.6%, with antibiotics accounting for the majority of these (44.6%) (16). Similar rates were also seen in the studies by Waffo Tchounga et al. (2021), Chiumia et al. (2022), and Maffioli et al. (2024) (25–27). Some of the highest rates of substandard and falsified medicines have been seen in Ghana, where in one study 66.4% of the total number of sampled antibiotics were seen as substandard (28, 29). Studies in Kenya also documented a 37.7% prevalence rate for substandard amoxicillin/co-amoxiclav (30). Falsified amoxicillin has also recently been reported in Cameroon and the Central African Republic (31). However, lower rates of falsified and substandard antimicrobials have been documented in other studies in Ghana and across Africa (32–35).

No counterfeit medicines were identified in South Africa in the study of Lehmann et al. (2018), with only a limited number seen in community outlets in practice Botswana and Namibia in recent years with their stricter controls regarding the supply and monitoring of medicines in these countries (36–38). In Botswana, there is a specific enforcement unit responsible for establishing and maintaining an effective import system for the Botswana Ministry of Health, with planned inspections increasing in recent years (39). The number of trained law enforcement officers helping with this activity has also increased in recent years in Botswana, which have resulted in greater confiscation of substandard medicines and other products in recent years (39). This included limited supplies of gentamicin and

TABLE 1 Definitions of the informal sector.

Study and year	Definition
Sudhinaraset et al., 2013 (51)	• Training, registration, and regulation: IPs typically have not received any formal training and are typically not recognized by formal institutions. They are usually outside of formal regulations and registration. • Payment: IPs typically collect payment directly from patients and usually, but not always, undocumented and in cash. IPs are chiefly entrepreneurs. • Professional affiliation: If these exist, they are usually centered on business activities with minimal self-regulation.
Liow et al., 2016 (52)	Unlicensed outlets
Schäfermann et al., 2020 (53)	Informal vendors do not include government health facilities, church health facilities, and community pharmacies.
Gautham et al., 2022 (49)	• IPs typically function out of small clinics and shops—alternatively via the itinerant and mobiles. • They charge a fee for services, which includes antibiotics, and typically without a prescription.
Rousham et al., 2023 (54)	They typically operate without a license, and the staff have minimal training regarding medicines.

IPs, informal providers.

tetracycline especially among informal vendors (39). Increased collaboration between the various government departments in Botswana, alongside coordinated law enforcement activities, has resulted in a 65% increase in the confiscation of goods and medicines in recent years, amounting to 35,097 units of various unauthorized regulated items principally from informal sellers (39, 40). Informal sellers are also being increasingly monitored in Botswana as an appreciable percentage of unregistered medicines are seen in this sector (39, 40). Personnel from the Botswana Police Department are also used to help disrupt the activities of informal sellers; however, the instigation of fines for illegal activities is currently limited (40).

Issues with substandard and falsified medicines in Africa are exacerbated by concerns with community pharmacists’ knowledge and practices on these issues (41, 42), coupled with high rates of dispensing of antibiotics without a prescription across a number of African countries (37, 43, 44).

Overall, substandard and falsified antibiotics can be found in both formal sectors, involving community pharmacies, and informal sectors across Africa (7). The informal sector plays an important role across Africa where higher rates of substandard and falsified antibiotics are seen compared with the situation in community pharmacies (45). This situation is exacerbated among African countries where the monitoring and control of medicine importation and distribution are generally currently limited (7, 39, 46–48). Typically where this occurs, informal sector for medicines outlets can be better stocked with medicines, including antibiotics, than government health facilities (49, 50). However, the informal sector is not evident, or only in limited numbers, in some African countries, including Namibia and South Africa, with their increasingly stricter controls. Definitions of the informal sector are documented in Table 1.

TABLE 2 Potential policy options to tackle falsified and substandard medicines.

Policy options	Suggested policy options
Governments/health authorities—focus and regulations	
Increase the national focus on substandard and falsified antibiotics as well as harmonize procedures across Africa. This includes addressing concerns with regulatory agencies where this occurs.	• Ensure that activities to reduce the extent of substandard and falsified antibiotics where these occur are prioritized as part of national action plans to reduce AMR (72). • This builds on WHO initiatives such as WHO Lomé Initiative as well as the development of Pan-African and regional initiatives to upgrade and harmonize regulatory activities and reduce duplication (18, 55, 58–60). In addition, coordinated activities with Interpol in Africa to track down suppliers of falsified antibiotics and prosecute them (73, 74). Coordinated activities resulted in seizures of counterfeit products, including medicines, across Southern Africa—estimated at US\$3.53 million—triggering over 300 criminal and administrative cases and 179 offenders apprehended, with similar activities in Western Africa (75). • Future activities should include instigating harmonized guidelines across Africa regarding the registration, inspection, and quality management of antibiotics as well as coordinated information management system (61). Alongside this, improved documentation where this is an issue—especially among African countries where there are currently substandard registration processes as well as possible corruption within agencies to allow substandard antibiotics to be marketed (19). • Instigate fines and potential imprisonment where corruption is seen between companies involved in providing falsified/substandard medicines and government personnel (76). • These combined activities should result in country health authority/regulatory personnel being released to enhance their monitoring of the quality of antibiotics dispensed in their country (61)—especially where there are concerns with limited inspections currently leading to increased availability of substandard/falsified antibiotics (19). • The number of law enforcement personnel and associated inspections have appreciably increased in Botswana in recent years—considerably reducing the chances of patients receiving substandard/falsified antibiotics (39)—acting as an exemplar to other African countries.
Toughen the laws surrounding substandard and falsified medicines including instigating fines	• Toughen the regulations and monitoring across Africa surrounding any locally produced API or finished products, as well as any multiple sourced antibiotics available among African countries, to make sure that they comply with agreed international standards. • Instigate compulsory re-registration and/or the removal of licenses by governments/health authorities where concerns with the supply of antibiotics are identified (16, 77). Improved co-ordination with Interpol should help in this regard to track down suppliers of falsified medicines (45). • Instigate additional sanctions for manufacturers/suppliers, as well as community pharmacies/informal suppliers, when falsified medicines are detected. This could again include removal licences, instigation of fines, disruption of sites where these antibiotics are sole, and potentially prison sentences (40, 74).
Focus licensing and production activities on priority antibiotics	• National/Pan-African licensing activities should be prioritized to focus on antibiotic needs in line with the increasing use of the WHO AWaRe system and prescribing guidance—subsequently adapted based on local resistance patterns (78–81). • This is because there has been over-registration of non-essential antibiotics among a number of African countries in recent years diverting regulatory resources away from registering essential antibiotics that help reduce AMR (82). • Focusing on essential antibiotics can feed into any strategic plans for increasing local production of antibiotics (78). Encouraging the prescribing of antibiotics and their doses based on the WHO AWaRe prescribing guidance should aid local production by only concentrating on a limited number of key antibiotics and doses thereby negating the need for multiple production lines and associated costs (7, 45). • The attractiveness of local antibiotic production can be enhanced through tariffs and other measures including reduced taxation (83, 84). However, such activities must be accompanied by increased transparency with pricing to help with issues of affordability/reduce the potential for unjustified price rises (84, 85).
Governments/health authorities—suggested additional national activities	
Explore the implementation of track-and-trace and other systems to improve the monitoring of antibiotics through the supply chain	• African countries should explore the potential for introducing pharmaceutical track-and-trace systems for antibiotics, building on the experiences in, for instance, Turkey where this system has worked well over a number of years (22, 45). • The first steps involve assessing the availability and use of digital systems, including mobile technologies in the country, the awareness of potential technology systems, current skill levels as well as digital/technical requirements/knowledge to implement such systems (19, 22, 86). This is particularly important across Africa where the routine availability and use of digital systems in monitoring the purchase and supply of antibiotics among the different types of drug stores is a concern. • The Indian government has also recently formed a task force to tackle issues with falsified medicines through a number of activities including instigating unique identification numbers and a bar code on medicine packs including antibiotics (71), although some problems persist (87). The Chinese Government has also recently introduced serialization and traceability requirements as well as promoting QR codes and RFID technologies for medicines in the country, including antibiotics, to combat counterfeit/falsified medicines (88). Both countries, along with Turkey, can provide guidance to African countries.
Encourage research into the extent and causes of substandard and falsified antibiotics and their impact on AMR to reduce future availability	• While a number of studies have been undertaken to try and document the extent of substandard and falsified antibiotics across Africa, which includes recent systematic reviews (14, 16, 25), there is an urgent need to build on these studies to provide real-time knowledge rather than “one-off” surveys, along with greater understanding of the causes behind the substantial provision of substandard and falsified medicines across Africa, to provide tailored solutions.

(Continued)

TABLE 2 Continued

Policy options	Suggested policy options
Governments/health authorities—suggested additional national activities	
	This can include addressing key factors such as affordability where patients struggle to obtain/fund antibiotics through PHCs and community pharmacies (7, 37).
Encourage research into cost-effective detection technologies as well as continue to monitor packaging developments	- Alongside this, there is a continuing need to encourage research among universities into cost-effective detection methods that can easily and readily be introduced across Africa to reduce the extent of falsified/substandard medicines alongside continuing to explore initiatives in packaging technologies such as track-and-trace systems (22, 46, 89, 90). - Continue to monitor developments in anti-counterfeit pharmaceutical packaging, and their suitability/affordability in Africa, to reduce the availability/use of falsified medicines (91). This includes developments such as RFID (88, 90, 92) as well as developments in hand-held spectrometry devices (19).
Encourage greater identification and monitoring of the quality of antibiotics dispensed among drug sellers and pharmacies	- Encourage community pharmacy personnel and other dispensers of antibiotics to inspect procured antibiotics for potential evidence of any substandard or falsified medicines by providing agreed checklists (93). Alongside this, encourage greater reporting of potential counterfeit antibiotics to the authorities when there are suspicions. - This will involve addressing knowledge gaps where they exist among dispensers concerning what to look for regarding packing/product information given current knowledge concerns—although this is not always the case (7, 76). - Alongside this, instigate/streamline communication channels where relevant information can quickly be disseminated—including how pharmacy/dispensing personnel can rapidly communicate suspicions to government/health authority personnel to help reduce these antibiotics reaching patients. - As a consequence, universities will need to appraise current curricula for community pharmacy/dispensing personnel—and update this where necessary—to improve identification and reporting of substandard/falsified antibiotics as well as instigate pertinent continual professional development activities post qualification (7).
Improving antibiotic supply chains including the potential for pooled procurement	- The first steps to improve supply chains involve encouraging greater rationality in the prescribing and dispensing of antibiotics among African countries—based on adapting the WHO AWaRe prescribing guidance according to local resistance patterns (78–80), alongside improving the quantification, stock management, forecasting, storage as well as distribution of antibiotics (94). - In addition, seek to instigate measures to streamline supply chains especially where these are currently complex/are an issue within African countries (19). - Important future considerations also include exploring the potential for pooled procurement networks for essential antibiotics across African regions/countries to lower their prices to governments/healthcare authorities and patients—thereby appreciably reducing the attractiveness of the falsified antibiotic market (7, 94)
Governments/health authorities—affordability and education	
Encouraging INN prescribing and dispensing to increase access to affordable antibiotics of agreed quality standards	- Encouraging the prescribing and dispensing of antibiotics based on their INN should appreciably reduce the number of available antibiotics among African countries especially those African countries where a substantial number of branded generic antibiotics are currently available. Such activities should result in appreciable lowering of the prices of antibiotics based on international experiences, e.g., low prices for generics are seen in the UK enhanced by high levels of voluntary INN prescribing and increased transparency with pricing (95–97). - Lower antibiotic prices should also help reduce the attractiveness of the market for substandard and falsified antibiotics. - However, enhancing the acceptance and use of INN prescribing requires health authorities to educate patients regarding the efficacy and safety of antibiotics available by their INN—as opposed to branded generics—provided they meet agreed standards—especially given concerns with unbranded generics among African countries (98, 99). - Reduced prices for quality antibiotics should reduce issues of affordability where this occurs thereby reducing the need for patients to seek antibiotics through the informal sector where there can be considerable concerns with their quality (7, 19, 37).
Enhancing AMR surveillance systems as part of NAPs and available guidelines	- Enhancing AMR surveillance systems across Africa. Reliable local resistance data can be used to adapt WHO AWaRe antibiotic guidance especially where there are concerns regarding the robustness and quality of locally produced antibiotic guidelines among African countries (63, 79, 100). - As a result, encourage HCPs and patients to be more careful about inappropriate antibiotic use and its consequences (7, 63). This should help reduce requests for antibiotics to be prescribed/dispensed especially among informal sellers—leading to a less attractive market for counterfeit antibiotics.
Drug sellers/community pharmacists and their assistants	
Improving knowledge and education surrounding substandard and falsified medicines	- Universities need to ensure that trainee pharmacists and licensed drug sellers are aware of key characteristics in packaging and inserts to identify substandard and falsified antibiotics and continue this post-qualification with continuous professional development activities - Alongside this, document key channels of communication for community pharmacists and formal drug sellers to be able to rapidly inform health authority personnel when they suspect that substandard and/or falsified antibiotics have been offered/sold to them.

AMR, antimicrobial resistance; API, active pharmaceutical ingredient; AWaRe, Access, Watch, and Reserve (101); HCPs, healthcare professionals; INN, international non-proprietary name; PHCs, primary healthcare centers; RFID, radio frequency identification; WHO, World Health Organization.

TABLE 3 Actional recommendations and their impact.

Policy options	Outcomes/implications
Governments/health authorities—coordinated Pan-African activities/working with other agencies	
Government/Ministry of Health personnel among African countries working together under a Pan-African regulatory agency to produce harmonized regulations and avoid duplication	• Build on ongoing activities throughout the African regions and across Africa to harmonize regulations regarding the licensing of medicines, thereby freeing staff to explore further the extent of substandard and falsified medicines across Africa and ways to reduce this—building on the World Health Organization’s “Lomé Initiative” and the Council of Europe’s Medicrime Convention Treaty (55, 56, 58, 59, 61, 62). • Alongside this, encourage improved documentation to meet agreed Pan-African standards where this is an issue—especially among African countries with current substandard registration processes/possible corruption within agencies allowing companies with substandard antibiotics to market these (19). • Ministries of Health among African countries can also learn from leading African regulatory agencies such as the Nigerian National Agency for Food and Drug Administration and Control and the Botswana Medicines Regulatory Authority with initiating multiple activities to identify and reduce the extent of substandard/counterfeit antibiotics (25, 39).
African countries working together with Interpol and other agencies to track down manufacturers of counterfeit antibiotics alongside toughening the laws surrounding these antibiotics	• Build on Interpol’s activities across Western and Southern Africa to track counterfeit medicines and apprehend offenders as part of the Illicit Goods and Global Health Program (45, 74, 75). • Interpol activities involving working with local government agencies in Southern Africa resulted in, e.g (73): - o Authorities in Eswatini seized more than 5,000 illicit pharmaceuticals after undertaking 3,780 checks. - o Authorities in Mozambique intercepted more than 32,300 illicit pharmaceuticals in Mozambique including antibiotics. - o Authorities in Zimbabwe seized more than 1,000 medicines and identified 83 suspects during the joint operations.
Governments/health authorities—national activities	
African countries to toughen sanctions for companies selling substandard/falsified antibiotics as well as the sellers of these antibiotics	• Governments, through their various agencies, should toughen current sanctions where falsified and substandard medicines are identified. These could include fines, disruption of facilities as well as potential imprisonment for manufacturers, distributors and sellers including informal sellers (74). • Alongside this, compulsory re-registration and/or the removal of licenses by governments/health authorities where there are concerns with substandard antibiotics (16, 77). • Such activities have worked well in China providing guidance to other countries including African countries (67–69).
African countries to continue to introduce digital systems as well as bar code and other mechanisms to track antibiotics through the system	• African countries can build on initiatives in China, India, and Turkey to instigate/expand pharmaceutical track and trace systems as well as insert unique identification numbers/bar codes on medicine packs including antibiotics to help limit the extent of falsified medicines (22, 71, 88). • This could also include governments promoting the use of QR codes and RFID technologies on medicines supplied to reduce their prevalence and associated public health concerns. • The first steps involve assessing the availability, awareness, and use of digital systems currently across Africa, including mobile technologies, current skill levels as well as digital/technical requirements/knowledge to implement such systems (19, 22, 86).
Encourage greater identification and monitoring of falsified antibiotics including improvements in packaging	• Alongside the introduction of track and trace systems, Ministry of Health personnel should also encourage community pharmacy personnel and other dispensers of antibiotics to regularly inspect procured antibiotics for potential evidence of substandard or falsified medicines by providing agreed checklists (93). • Combined with this, encourage greater reporting of potential counterfeit antibiotics to the authorities through streamlining communication channels where relevant information can quickly be disseminated to appropriate government/health authority personnel. • In addition, government/health authority personnel should continue to monitor developments in anti-counterfeit pharmaceutical packaging, and their suitability/affordability, across Africa to help reduce the availability/use of falsified antibiotics as well as identify them when supplied (91).
African countries to improve supply chains and forecasting to reduce costs as well as explore pooled procurement	• Currently, there can be concerns with complex supply chains across countries. • Future steps involve the following: - o Government/Ministry of Health personnel instigating initiatives to restrict the prescribing and dispensing of antibiotics, including doses, to an agreed list of antibiotics based on the WHO AWaRe guidance, which will also facilitate local production as well as potentially pooled procurement across countries (7, 19, 63, 78, 79, 94). - o Improving the quantification, stock management, forecasting, storage as well as distribution of antibiotics where there are concerns (94, 102). - o Seeking to streamline supply chains where there are concerns increasing the costs and reducing the availability of key antibiotics (19). • These combined measures should help lower the costs of antibiotics, thereby reducing the attractiveness of producing and distributing falsified antibiotics.
Focus local production of antibiotics onto critical antibiotics and doses to reduce production costs	• African governments should take steps to encourage greater local production of antibiotics among African countries where this already occurs.

(Continued)

TABLE 3 Continued

Policy options	Outcomes/implications
Governments/health authorities—national activities	
	- Alongside this, there should be accompanying activities to encourage the prescribing and dispensing of only a limited number of antibiotics and doses through the greater use of WHO AWaRe guidance (7, 63, 79). As a result, helping to reduce production costs by focusing production only on critical antibiotics and doses. - However, any introduction of tariffs and other measures, including reduced taxation, to encourage local production (83, 84), must be accompanied by increased pricing transparency to reduce the potential for unjustified price increases (84, 85).
Governments/health authorities—national educational and university activities	
Encourage INN prescribing to reduce confusion, improve supply chains and reduce costs	- Encouraging INN prescribing will appreciably reduce the number and associated costs of branded generics based on the experiences in countries where there are high rates of INN prescribing combined with aggressive initiatives to lower costs (96). - For instance, in Pakistan, there are currently 2,186 brands of generic cephalosporins in the market with 6,447 presentations and 1,333 brands of generic quinolones with 2,586 presentations, adding to the costs of multiple-sourced antibiotics in the market—all seeking to make a profit (95, 96, 103). Such situations need to be urgently addressed to reduce the attractiveness of the market for falsified antibiotics. - However, all key stakeholders need to have faith in the quality of generic antibiotics available in a country to enhance INN uptake given the current concerns of their quality among LMICs (96, 98). Governments and universities can play a key role here with educating all relevant stakeholders of the quality of available generics with improved monitoring
African universities to encourage further research into the prevalence of falsified antibiotics and their rationale as well as general knowledge surrounding substandard and falsified medicines among dispensers	- African universities can work with key organizations globally and nationally, including the WHO and others, to better understand the current prevalence of substandard and falsified antibiotics across Africa and the rationale behind their continued use. - This includes the extent of deaths due to falsified and substandard antibiotics, including AMR, building on the experiences in Nigeria (21). - Alongside this, improve their working with pertinent government departments to enhance the education of pharmacy/pharmacy assistant undergraduates regarding key aspects of substandard/falsified antibiotics, including their identification and reporting. This will mean universities critically evaluating their current curricula to see if this is fit for the purpose.

AMR, antimicrobial resistance; AWaRe, Access, Watch and Reserve (101); INN, international non-proprietary name; LMIC, low- and middle-income country; RFID, radio frequency identification; WHO, World Health Organization.

To date, principal initiatives to reduce the prevalence of substandard and falsified medicines across Africa have been centered on regulatory activities (45). These include the World Health Organization's (WHO) "Lome' Initiative" alongside the development of an African Medicines Agency (7, 18, 55–60), building on the ongoing efforts among the East African community (61). Governments within several African countries have also endorsed the Council of Europe's Medicrime Convention Treaty to help reduce the extent of substandard and falsified medicines (7, 62). We are also seeing leading agencies such as the Nigerian National Agency for Food and Drug Administration and Control initiating multiple activities to reduce the problem (25).

Potential ways forward to reduce the extent of substandard and falsified antibiotics across Africa are discussed in Section 2, which is based on the considerable knowledge of the co-authors. The potential activities include governments and health authorities instigating multiple activities across Africa. The suggested activities include a continued focus on substandard and falsified medicines, including antibiotics, prioritizing the registration of essential antibiotics and away from all antibiotics, undertaking greater monitoring of drug stores and community pharmacies as well as instigating fines where there are concerns with the quality of dispensed antibiotics. Alongside this, reducing the current high levels of inappropriate prescribing and dispensing of antibiotics currently seen across Africa (7, 37, 63, 64). In addition, greater education of all key stakeholder groups to help

identify and report substandard and falsified medicines (65, 66). Focusing and encouraging the appropriate use of only essential antibiotics will also reduce the attractiveness of this market and subsequently improve public health (7).

We are seeing, for instance, LMICs such as China making appreciable progress with improving the quality of their locally produced multiple-sourced medicines, including antibiotics, with appreciable penalties when substandard and falsified medicines are found (67–69). We are also seeing countries such as India and Pakistan instigate a number of measures, including bar coding on packs of antibiotics, in an attempt to reduce the prevalence of counterfeit medicines (70, 71). Similarly, in Botswana, there has been increased monitoring of facilities, including among informal sellers, to disrupt this market (39, 40).

2 Policy options to reduce the extent of substandard and falsified medicines across Africa

A number of policy options have been proposed to reduce the extent of substandard and falsified medicines across Africa. These include activities aimed at both the formal and informal sectors (Table 2), and involve initiatives by governments which includes

enhancing current regulations as well as other initiatives to reduce the extent of substandard and falsified medicines.

Ongoing initiatives among all key stakeholder groups to reduce the high levels of inappropriate prescribing and dispensing of antibiotics seen among African countries, thereby reducing the attractiveness of marketing substandard and falsified antibiotics, are discussed elsewhere in this Frontiers Special Issue as well as by Saleem et al. (2025) (7, 63). Consequently, they will not be part of Table 2.

3 Actionable recommendations

The actionable recommendations (Table 3) are based on their impact where known in published studies across LMICs, including African countries, combined with the considerable experience of the co-authors. As mentioned, initiatives to reduce inappropriate prescribing and dispensing of antibiotics, thereby reducing the attractiveness of the substandard and falsified antibiotics market, are discussed elsewhere in this Frontiers Special Issue as well as in Saleem et al. (2025) (7, 63). Similar to the data in Table 2, this will include activities surrounding regulations as well as other initiatives to reduce the extent of substandard and falsified medicines across Africa.

We are aware of a number of limitations with our policy brief. This primarily includes the fact that we have not undertaken a systematic review. However, we have undertaken a narrative review including examples of potential policy options to tackle falsified and substandard medicines followed by potential actionable recommendations. The guidance is based on the considerable experience of the co-authors working across Africa and other LMICs. We have successfully used this approach before (7, 37, 63, 104).

4 Conclusions

Addressing Africa's battle against substandard and falsified antibiotics to reduce AMR requires integrated, scalable, and context-specific policies to address gaps in regulation, enforcement, education, affordability, and supply chain monitoring. This builds on ongoing initiatives among the WHO, Interpol and Pan-African agencies as well as exemplars in other LMICs. Reducing high levels of inappropriate use of antibiotics across Africa, alongside encouraging INN prescribing with appropriate safeguards, will also help reduce the attractiveness of the counterfeit antibiotic market. These combined activities will help address high levels of AMR across Africa.

Author contributions

TM: Investigation, Data curation, Methodology, Writing – review & editing, Conceptualization, Validation, Formal analysis,

Writing – original draft. BM: Writing – review & editing, Formal analysis, Investigation, Data curation, Methodology, Writing – original draft, Conceptualization. CU: Data curation, Methodology, Formal analysis, Validation, Writing – review & editing. BP: Writing – review & editing, Validation, Formal analysis, Methodology. MM: Investigation, Writing – review & editing, Validation, Methodology, Formal analysis. AK: Writing – review & editing, Investigation, Formal analysis, Validation, Data curation. EH: Writing – review & editing, Formal analysis, Data curation, Validation, Investigation, Visualization. SK: Formal analysis, Data curation, Validation, Investigation, Writing – review & editing. BG: Investigation, Data Curation, Methodology, Conceptualization, Formal analysis, Validation, Writing – original draft, Writing – review & editing, Supervision. JM: Writing – review & editing, Visualization, Conceptualization, Methodology, Supervision, Investigation, Validation.

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