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# Surge of branded generics and antimicrobial resistance: analyzing the antibiotic market dynamics in Pakistan through the WHO essential medicines and AWaRe lens

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**ABSTRACT**

**Background:** Access to safe and effective antibiotics is crucial in low- and middle-income countries (LMICs) coupled with reducing their overuse to reduce antimicrobial resistance (AMR). We sought to systematically analyze the extent of branded generic antibiotics in Pakistan, particularly Watch antibiotics, given concerns with AMR in Pakistan.

**Research design and methods:** Data on registered antibiotics was collected from the Drug Regulatory Authority of Pakistan (DRAP) and the Pharmaguides. Two hundred and fifty-seven antibiotics were analyzed using the AWaRe classification.

**Results:** Of these, 99 were registered in Pakistan including 91 single entities and 8 combinations, with 6,025 brands and 14,076 presentations. Distribution across AWaRe categories included Access – 37, Watch – 56, and Reserve – 6. Cephalosporins (2186 brands, 6447 presentations) and Quinolones (1333 brands, 2586 presentations) are the most prevalent, with ciprofloxacin (393 brands, 1158 presentations) leading in brand and presentation counts. Six antibiotics from the WHO Essential Medicines List lacked registered brands in Pakistan, while many available antibiotics were not included in the WHO framework.

**Conclusion:** Extensive availability of branded generic antibiotics, particularly Watch antibiotics, in Pakistan poses a serious risk, exacerbated by the current misuse of antibiotics. Improving regulatory frameworks and strengthening stewardship are critical to reducing AMR in Pakistan along with addressing uncontrolled registration by DRAP.

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Generics; antibiotics; branded generics; registration; AWaRe; pharmaceutical policy; antimicrobial resistance; Pakistan

## 1. Introduction

Ensuring equitable access to medicines is a central theme of the Sustainable Development Goals (SDGs), with SDG 3.8 explicitly highlighting 'access to safe, effective, quality, and affordable essential medicines and vaccines for all' as a fundamental element of universal health coverage (UHC) [1]. Currently, though approximately 2 billion people globally are deprived of essential medicines, particularly in lower- and middle-income countries (LMICs) [2]. Conversely, there are considerable concerns with antibiotic overuse in LMICs driving up antimicrobial resistance (AMR) rates, with an associated increase in morbidity and mortality [3–5]. This is especially the case in LMICs where access to quality healthcare can be limited and with limited regulations and monitoring surrounding the ready availability and quality of multiple sourced medicines [6–9]. In 2019, it was estimated that bacterial AMR directly caused 1.27 million deaths globally and contributed to a total of 4.95 million deaths, with these figures envisaged to appreciably increase unless addressed [4,5].

Pakistan is currently the third-largest consumer of antibiotics in LMICs after China and India [10]. Alongside this, AMR is currently the third leading cause of death in Pakistan, accounting for approximately 700,000 deaths annually [11], with increasing emergence of multi-drug resistant pathogens, with AMR rates continuing to rise unless addressed [12–15]. There are ongoing activities to reduce AMR rates in Pakistan contained within its National Action Plan of Pakistan, building on the World Health Organization's (WHO) global action plan [16–18]. Other global initiatives orchestrated by the WHO to reduce AMR include classifying antibiotics into Access, Watch and Reserve antibiotics (AWaRe), with the emphasis on reducing the utilization of Watch and Reserve antibiotics with their greater resistance potential where this occurs [19–21]. The widespread misuse of broad spectrum antibiotics, particularly those in the WHO Watch list, are a particular concern in LMICs

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driving the increase in AMR [6,22–24]. As a result, The United Nations General Assembly (UNGA) recommended that at least 70% of antibiotics should now be from the Access group [25]

However in Pakistan, where physicians often lack sufficient knowledge on appropriate antibiotic prescribing [26–28], there was a 61.5% increase in the use of antibiotics from the WHO Watch group between 2014 and 2018 [29]. This increase, combined with widespread inappropriate antimicrobial use (AMU) and a culture of self-medication, including obtaining antibiotics without prescriptions, has exacerbated AMR in Pakistan including among commonly used antimicrobials [14,15,26,30–33]. In one study in Punjab, 96.9% of community pharmacies dispensed antibiotics without a prescription [30]. As a result, Pakistan is one of the top five countries with the highest neonatal deaths attributed to resistant bacteria [34], with, as mentioned, AMR currently the third leading cause of death in Pakistan [11].

The Pakistan NAP identified several factors that have contributed to AMR in the country. First, the Pakistani market had an excessively high number of antibiotics available, which included multiple branded generics from local manufacturers, with more than 76,000 brands of all medicines currently available [35]. This situation is not helped by an appreciable number of local manufacturers of generics in Pakistan, with over 600 operating in 2018 [35]. This is a concern as there are issues regarding the quality and safety of medicines in Pakistan including antibiotics, with suboptimal monitoring of their quality by the Drug Regulatory Authority of Pakistan (DRAP) [8,35–41]. DRAP is responsible for regulating and overseeing the pharmaceutical sector in Pakistan. Its key functions include drug registration, market surveillance, licensing of manufacturers, monitoring clinical trials, and ensuring the safety and efficacy of medicines through pharmacovigilance [42]. However, the current situation is quite challenging in Pakistan since branded generics can currently be registered without the requirement for bioequivalence studies [43,44]. There are also concerns regarding the promotional activities among pharmaceutical companies in Pakistan, coupled with a lack of regulatory oversight on marketing and sales activities, potentially driving up antibiotic use including Watch antibiotics [45].

Alongside this, concerns if different branded generics have different names causing confusion when different ones are prescribed unless pharmacists spend time talking with patients [46,47]. This is especially an issue in countries such as Pakistan where patients generally have limited knowledge regarding antibiotics, their effectiveness for different infectious diseases and AMR [28,41,48–50]. In addition, previous studies have shown that the higher the number of antibacterial trade names available, the greater are consumption rates, indicating that approving multiple similar agents will increase usage and worsen AMR [51]. As a result, high rates of Watch antibiotics are often being prescribed and sold without a prescription in Pakistan, including during the recent COVID-19 pandemic, exacerbated by the appreciable number of Watch antibiotics readily available and being recommended in Pakistan [29,30,32,52–54]. Moreover, prescribers, pharmacists and other healthcare providers in Pakistan are expected to face increased marketing pressure due to competing brands' marketing strategies, and the increased number of brands for one generic medicine that is often available, with sometimes the only education physicians receive regarding antibiotics is from pharmaceutical companies [45,55,56].

Consequently, the proliferation of branded generics in Pakistan's pharmaceutical market, including those from the Watch list, will have appreciable implications for continuing to increase AMR in Pakistan. As a result, posing a challenge to public health and achieving the NAP goals in Pakistan. However, before suggesting possible future strategies to address current concerns, there is an urgent need to assess the current availability of branded generic antibiotics in Pakistan by their WHO AWaRe category, which builds on the studies of Malik and Figueras (2019) and Rafi et al (2024) [52,57]. This especially includes branded generic antibiotics from the WHO Watch list given current concerns. The findings can be used to suggest future activities among all key stakeholder groups to achieve NAP and UN GA goals in Pakistan.

## 2. Methods

### 2.1. Data source and collection

Data was collected from the DRAP website [58], the Pharmaguide book, and the Pharmaguide app (Edition 2024). Pharmaguide Pakistan, which has been published for over 35 years, serves as a comprehensive directory and reference guide for the pharmaceutical industry [59]. It consolidates detailed information about pharmaceutical products and companies operating in the country. Published by a group of pharmacists, it is recognized for its accuracy and breadth. The platform is funded through a combination of advertising, subscription services, and partnerships with pharmaceutical companies and industry stakeholders. Regularly updated, the Pharmaguide serves as a key directory for the pharmaceutical sector, maintaining strong links to the industry. It is particularly valuable for examining the current landscape of antibiotics in Pakistan.

Data extraction focused on branded generic antibiotics, including information on their classification, the number of brands, and the different forms of presentations available. In our study, we analyzed all 257 antibiotics from the WHO AWaRe Classification 2023 [19,21]. This selection included 87 antibiotics from the Access group, 141 from the Watch group, and 29 from the Reserve group.

### 2.2. Inclusion criteria

For each antibiotic registered in Pakistan, we counted the available brands and presentations including peroral and parenteral preparations. However, topical presentations were excluded, as the focus of the article was to link the data with AMR. The latest update of the WHO AWaRe (Access, Watch, and Reserve) classification of antibiotics available at the time of the study, released in 2023, was used to categorize antibiotics into three groups to guide their use and minimize resistance [60].

### 2.3. Definitions

Innovator brands refer to the original commercially marketed products developed and patented by a pharmaceutical company, and are typically marketed under a proprietary, trademark-protected name.

After the patent expires, other manufacturers can produce the same drug as generics. Branded generics are generic medicines, i.e. multiple sourced medicines, that have been given a specific brand name by the manufacturer. These medicines have no exclusivity unlike the originator brand when still patented.

Presentations in the context of pharmaceuticals refer to the different forms in which a drug is manufactured, which can include tablets, capsules, liquids (solutions and suspensions) and injectables. The WHO AWaRe tool categorizes antibiotics into three groups: Access antibiotics that have activity against a wide range of commonly encountered pathogens and have a lower risk of promoting AMR, and are typically recommended as first- or second-choice treatments for specific infections [21,24,60]. Watch antibiotics have a higher resistance, with Reserve antibiotics reserved for the treatment of confirmed or suspected infections due to multi-drug resistant organisms.

### 2.4. Data analysis and recommendations

Initial analysis involved descriptive statistics to provide an overview of the number of brands and presentations for each antibiotic, categorized by their AWaRe classification. We conducted a trend analysis to identify changes in the number of branded generics and presentations according to WHO ATC classification over time [61]. This analysis was performed to enhance understanding of the market dynamics for antibiotics in Pakistan and potential pressures on AMR. The data was also compared against the WHO Essential Medicines List (EML), including the AWaRe classification, to ascertain discrepancies and alignment with international health standards [21,60]. The recommendations for all key stakeholders will be based on the considerable experience of the coauthors in similar situations [15,35,62–65].

### 2.5. Ethical considerations

This study does not involve human subjects or clinical trials, and as such, did not require ethical approval. However, all data handling was conducted to ensure confidentiality and integrity in accordance with standard research practices.

## 3. Results

A total of 257 antibiotics from the WHO AWaRe classification were analyzed. Among these, 241 are classified as single entities, while 16 were combinations that include multiple active ingredients. In Pakistan, 99 of these 257 antibiotics have been officially registered for use, which includes 91 single entity antibiotics and 8 combination products. Among the registered antibiotics in Pakistan, 37 belong to the Access group, 56 belong to the Watch group and 6 are part of the Reserve group.

The registered antibiotics are associated with approximately 6,025 different brands and 14,076 presentations, reflecting a wide variety of formulations and dosage options currently available in the market in Pakistan (Table 1 and Figure 1).

Cephalosporins (J01D) represent the largest group of antibiotics registered in Pakistan, based on the number of brands and presentations, followed by the quinolones/fluoroquinolones (J01M). A total of 23 antibiotics from cephalosporin group are currently registered in Pakistan, with 2,186 brands and 6,447 presentations available (Table 2).

The highest number of presentations and brands for a single antibiotic was for ciprofloxacin (J01MA02), with 1,158 presentations and 393 brands. This was followed by ceftriaxone, which had 1,064 presentations and 256 brands, and azithromycin, with 960 presentations and 368 brands (Table 3).

It was also noted that among the antibiotics included in the WHO EML, six have no registered brands available in Pakistan. On the other hand, there were 60 antibiotics currently available in Pakistan that are not included in the WHO EML. These antibiotics come with multiple brands and presentations, indicating a wide range of options in the market (Table 4). The results also identified a few antibiotics and combinations of antibiotics that are not classified in the WHO AWaRe classification but are also available in Pakistan (Table 5). This highlights the presence of additional antibiotic options in the market that do not fall within the established global framework.

### 3.1. Discussion

We believe this is the first study conducted in Pakistan to comprehensively document the number of branded antibiotics available, especially those from the Watch and Reserve categories, building on the earlier studies of Malik and Figueras [52]. This endorses concerns outlined in the Pakistan NAP on AMR (2017), highlighting major challenges including the appreciable number of registered antimicrobials [16].

In Pakistan, the emergence of AMR is influenced by both social factors and patterns of antimicrobial usage, with key social factors including poverty, misinformation, and cultural practices [53,66,67]. These factors, alongside considerable

Table 1. Antibiotics market of Pakistan.

| Category | Access | Watch | Reserve | Total |
|---|---|---|---|---|
| Mentioned in AWaRe Classification | 87 | 141 | 29 | 257 |
| Not Registered in Pakistan | 50 | 85 | 23 | 158 |
| Registered in Pakistan | 37 | 56 | 6 | 99 |
| Brands | 1454 | 4339 | 232 | 6025 |
| Average number of Brands per Generic | 40 | 78 | 39 | 61 |
| Presentations/Formulations | 3459 | 10108 | 509 | 14076 |
| Average number of Presentations/ Formulations per Generic | 94 | 181 | 85 | 142 |
| Status of Registration of Antibiotics Listed in EML | | | | |
| No of Drugs | 22 | 13 | 4 | 39 |
| Brands | 1008 | 2233 | 207 | 3448 |
| Presentations/Formulations | 2054 | 6228 | 483 | 8765 |

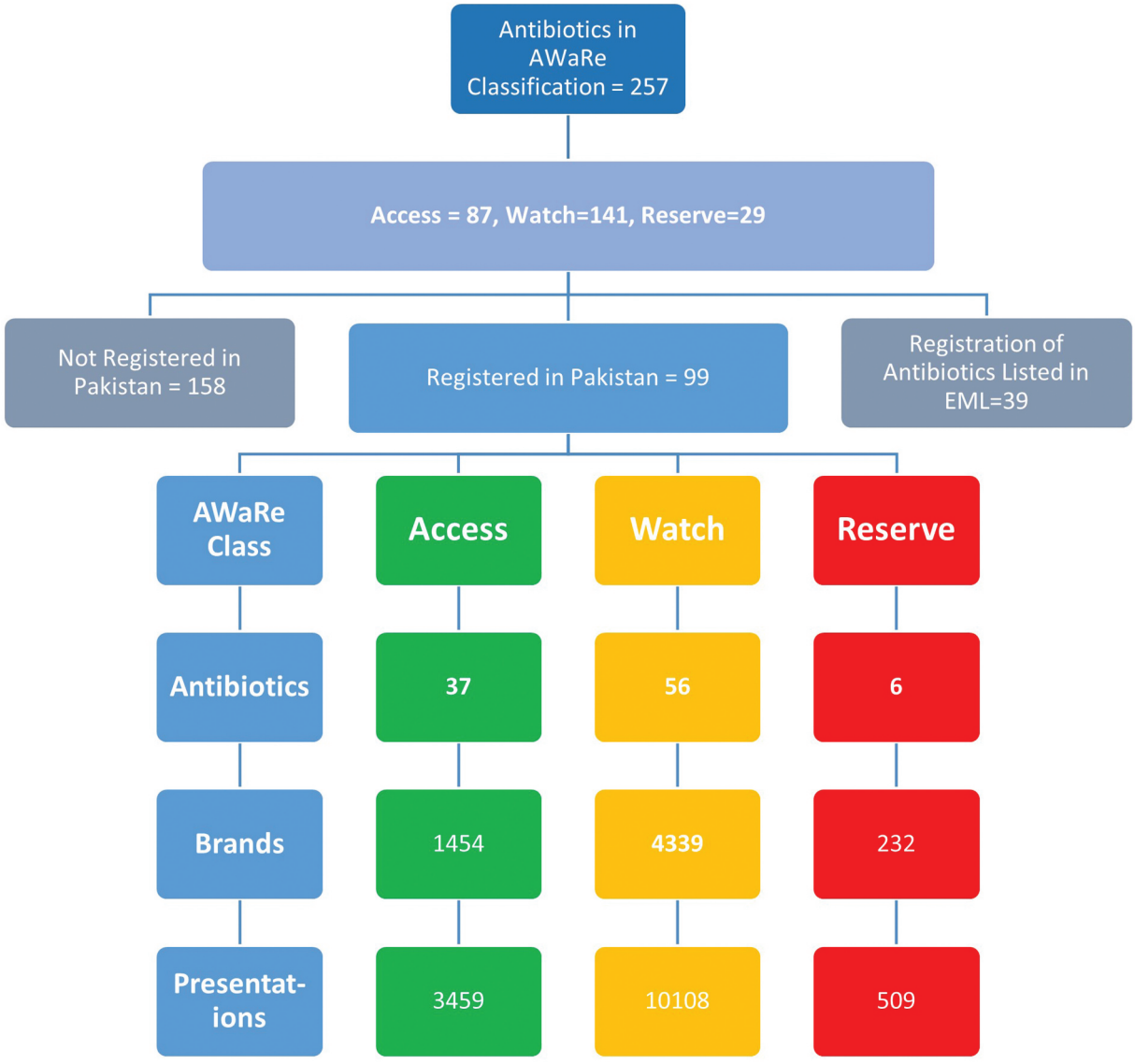


Figure 1. Consort diagram.

availability of different branded generics with varying quality, including those from the WHO Watch and Reserve list, need to be addressed to improve future utilization and reduce AMR [41,51,68]. Overall, the appreciable presence of Watch antibiotics in a market, which already includes numerous antibiotic combinations, both rational and irrational, raises significant concerns for policymakers and regulators in Pakistan as they seek to reduce AMR in line with the goals of the NAP [17]. This is a challenge with patients readily dispensed antibiotics from the WHO Watch group often without a formal prescription in Pakistan and often for self-limiting conditions [27,30,32,53,66].

Alongside this, antibiotics are among the most commonly counterfeited medicines across the world, accounting for 28% of global counterfeit drugs [41]. In addition to posing serious health risks to patients, counterfeit medicines contribute to the development of AMR, with widespread global implications [41,69]. According to the NAP of Pakistan, it is recommended that the government implement tighter regulations to reduce the availability of substandard branded antibiotics. The need for tighter regulations in Pakistan are enhanced by the significant number of different branded antibiotics that are available in Pakistan, including those from the Watch list. This involves increasing Good Manufacturing Practice (GMP) inspections among manufacturers, enhancing analytical laboratory capabilities, and building capacity to reduce the extent of substandard and falsified medicines in Pakistan including antibiotics [37,41]. Overall, the Government needs to strengthen DRAP to enforce stricter antibiotic registration processes as well as reduce the excessive number of brands currently available for each antibiotic. Establishing clear prescribing and dispensing policies is also crucial to guide all healthcare professionals in the responsible use of antibiotics [41,62,65,70]. Implementing antimicrobial stewardship programs (ASPs) will further promote prudent prescribing and dispensing practices [41,65,70]. These should increasingly be based on the WHO AWaRE guidance and indicators [70,71].

Introducing incentives to pharmacists and patients to dispense INN antibiotics provided they meet the standards of the EMA, alongside encouraging INN prescribing, should also help where there are issues of affordability for antibiotics among

Table 2. Registered antibiotics according to classification.

| Class | ATC Code | No of Drugs | Brands | % | Presentation | % | Average No of brands per generic | Average No of Presentations per generic |
|---|---|---|---|---|---|---|---|---|
| Cephalosporins | J01D | 23 | 2186 | 36.28 | 6447 | 45.80 | 95 | 280 |
| Quinolones | J01M | 14 | 1333 | 22.12 | 2586 | 18.37 | 95 | 185 |
| Macrolides | J01FA | 6 | 813 | 13.49 | 1979 | 14.06 | 136 | 330 |
| Imidazoles | J01XD | 4 | 330 | 5.48 | 596 | 4.23 | 83 | 149 |
| Oxazolidinones | J01XX | 1 | 188 | 3.12 | 454 | 3.23 | 188 | 454 |
| Penicillins | J01RA01 | 10 | 149 | 2.47 | 346 | 2.46 | 15 | 35 |
| Aminoglycosides | J01G | 5 | 138 | 2.29 | 288 | 2.05 | 28 | 58 |
| Tetracyclines | J01AA | 6 | 174 | 2.89 | 201 | 1.43 | 29 | 34 |
| Sulfonamide-trimethoprim-combinations | J01E | 3 | 108 | 1.79 | 200 | 1.42 | 36 | 67 |
| Lincosamides | J01FF | 2 | 132 | 2.19 | 191 | 1.36 | 66 | 96 |
| Carbapenems | J01DH | 4 | 100 | 1.66 | 177 | 1.26 | 25 | 44 |
| Rifamycins | J01FA | 2 | 96 | 1.59 | 177 | 1.26 | 48 | 89 |
| Glycopeptides | J01XA | 2 | 57 | 0.95 | 106 | 0.75 | 29 | 53 |
| Beta-lactam/beta-lactamase-inhibitor | J01C | 3 | 46 | 0.76 | 96 | 0.68 | 15 | 32 |
| Beta-lactam/beta-lactamase-inhibitor_anti-pseudomonal | J01C | 1 | 35 | 0.58 | 63 | 0.45 | 35 | 63 |
| Phosphonics | J05AD | 2 | 48 | 0.80 | 62 | 0.44 | 24 | 31 |
| Amphenicols | J01B | 2 | 24 | 0.40 | 30 | 0.21 | 12 | 15 |
| Glycylcyclines | J01A | 1 | 24 | 0.40 | 25 | 0.18 | 24 | 25 |
| Polymyxins | J01XB | 1 | 13 | 0.22 | 19 | 0.13 | 13 | 19 |
| Nitrofuran-derivatives | J01XE | 1 | 12 | 0.20 | 12 | 0.09 | 12 | 12 |
| Sulfonamide | QJ01EQ | 3 | 8 | 0.13 | 9 | 0.06 | 3 | 3 |
| Steroid antibacterials | J01XC | 1 | 7 | 0.12 | 8 | 0.06 | 7 | 8 |
| Trimethoprim-derivatives | J01EA | 1 | 3 | 0.05 | 3 | 0.02 | 3 | 3 |
| Aminocyclitols | J01G | 1 | 1 | 0.02 | 1 | 0.01 | 1 | 1 |

Table 3. Top 25 antibiotics with highest numbers of presentations and brands.

| Antibiotic | Class | ATC Code | Category | Brands | % | Presentations | % | No of Presentations per brand |
|---|---|---|---|---|---|---|---|---|
| Ciprofloxacin | Fluoroquinolones | J01MA02 | Watch | 393 | 6.52 | 1158 | 8.23 | 3 |
| Ceftriaxone | Third-generation-cephalosporins | J01DD04 | Watch | 256 | 4.25 | 1064 | 7.56 | 4 |
| Azithromycin | Macrolides | J01FA10 | Watch | 368 | 6.11 | 960 | 6.82 | 3 |
| Cefixime | Third-generation-cephalosporins | J01DD08 | Watch | 288 | 4.78 | 852 | 6.05 | 3 |
| Cefradine | First-generation-cephalosporins | J01DB09 | Access | 211 | 3.50 | 799 | 5.68 | 4 |
| Clarithromycin | Macrolides | J01FA09 | Watch | 302 | 5.01 | 772 | 5.48 | 3 |
| Levofloxacin | Fluoroquinolones | J01MA12 | Watch | 248 | 4.12 | 570 | 4.05 | 2 |
| Cefaclor | Second-generation-cephalosporins | J01DC04 | Watch | 143 | 2.37 | 533 | 3.79 | 4 |
| Metronidazole (Oral-IV) | Imidazoles | P01AB01 J01XD01 | Access | 293 | 4.86 | 530 | 3.77 | 2 |
| Cefadroxil | First-generation-cephalosporins | J01DB05 | Access | 163 | 2.71 | 481 | 3.42 | 3 |
| Cefotaxime | Third-generation-cephalosporins | J01DD01 | Watch | 166 | 2.76 | 475 | 3.37 | 3 |
| Linezolid | Oxazolidinones | J01XX08 | Reserve | 188 | 3.12 | 454 | 3.23 | 2 |
| Cefoperazone | Third-generation-cephalosporins | J01DD12 | Watch | 169 | 2.80 | 423 | 3.01 | 3 |
| Cefalexin | First-generation-cephalosporins | J01DB01 | Access | 109 | 1.81 | 364 | 2.59 | 3 |
| Moxifloxacin | Fluoroquinolones | J01MA14 | Watch | 306 | 5.08 | 356 | 2.53 | 1 |
| Cefuroxime | Second-generation-cephalosporins | J01DC02 | Watch | 106 | 1.76 | 299 | 2.12 | 3 |
| Ofloxacin | Fluoroquinolones | J01MA01 | Watch | 199 | 3.30 | 297 | 2.11 | 1 |
| Cefepime | Fourth-generation-cephalosporins | J01DE01 | Watch | 141 | 2.34 | 296 | 2.10 | 2 |
| Ceftazidime | Third-generation-cephalosporins | J01DD02 | Watch | 128 | 2.12 | 218 | 1.55 | 2 |
| Sulfamethoxazole/ Trimethoprim | Sulfonamide-trimethoprim-combinations | J01EE01 | Access | 105 | 1.74 | 195 | 1.39 | 2 |
| Cefpodoxime-proxetil | Third-generation-cephalosporins | J01DD13 | Watch | 105 | 1.74 | 181 | 1.29 | 2 |
| Amikacin | Aminoglycosides | J01GB06 | Access | 70 | 1.16 | 180 | 1.28 | 3 |
| Lincomycin | Lincosamides | J01FF02 | Watch | 105 | 1.74 | 156 | 1.11 | 1 |
| Rifaximin | Rifamycins | A07AA11 | Watch | 78 | 1.29 | 140 | 0.99 | 2 |
| Doxycycline | Tetracyclines | J01AA02 | Access | 109 | 1.81 | 122 | 0.87 | 1 |

patients [35,46]. Concomitant with this, educational campaigns should also be launched among patients to promote the effectiveness of unbranded (INN) generics, demonstrating that they are as reliable and effective as branded options [46]. Such campaigns can help lower prices and improve access, especially where affordability is a concern [35,46]. For instance, Sandoz's 'Ask for Generics' campaign in the US successfully raised awareness of generics' benefits, showing how they improve access to medicines and generate savings for patients and the healthcare system [72].

The current drug laws in Pakistan, particularly those concerning antibiotics, also need revising to ensure they incorporate antibiotics recommended in the WHO AWaRe book, and better align with local resistance patterns [62,73,74]. The existing list of antibiotics in Schedule D of the Drug Law is incomplete, omitting crucial antibiotic classes and essential medications for treating multi-drug-resistant infections, while inexplicably including the tricyclic antidepressant amitriptyline [62]. Furthermore, the implementation of these laws has generally been ineffective,

Table 4. Top 10 antibiotics not listed in WHO EML but available in Pakistan.

| Antibiotic | Class | ATC Code | Category | Brands | % | Presentations | % | No of Presentations per brand |
|---|---|---|---|---|---|---|---|---|
| Cefradine | First-generation-Cephalosporins | J01DB09 | Access | 211 | 3.50 | 799 | 5.68 | 4 |
| Levofloxacin | Fluoroquinolones | J01MA12 | Watch | 248 | 4.12 | 570 | 4.05 | 2 |
| Cefaclor | Second-generation-cephalosporins | J01DC04 | Watch | 143 | 2.37 | 533 | 3.79 | 4 |
| Cefadroxil | First-generation-Cephalosporins | J01DB05 | Access | 163 | 2.71 | 481 | 3.42 | 3 |
| Cefoperazone | Third-generation-cephalosporins | J01DD12 | Watch | 169 | 2.80 | 423 | 3.01 | 3 |
| Moxifloxacin | Fluoroquinolones | J01MA14 | Watch | 306 | 5.08 | 356 | 2.53 | 1 |
| Ofloxacin | Fluoroquinolones | J01MA01 | Watch | 199 | 3.30 | 297 | 2.11 | 1 |
| Cefepime | Fourth-generation-cephalosporins | J01DE01 | Watch | 141 | 2.34 | 296 | 2.10 | 2 |
| Cefpodoxime-proxetil | Third-generation-cephalosporins | J01DD13 | Watch | 105 | 1.74 | 181 | 1.29 | 2 |
| Lincomycin | Lincosamides | J01FF02 | Watch | 105 | 1.74 | 156 | 1.11 | 1 |

Table 5. Combinations/Drugs not listed in AWaRE classification but registered in Pakistan.

| Antibiotic | Brands | Presentation |
|---|---|---|
| Ampicillin/Flucloxacillin | 3 | 6 |
| Ampicillin/Cloxacillin | 13 | 31 |
| Piperacillin/Sulbactum | 1 | 1 |
| Sulbactum/Amoxicillin | 1 | 1 |
| Ticarcillin/Clavulanic Acid | 1 | 1 |
| Cefoperazone/Sulbactum | 90 | 178 |
| Imipemide | 12 | 15 |

leading to the unrestricted availability of antimicrobials in Pakistan including among drug sellers. This, combined with the high rates of dispensing of WHO Watch (49.3%) and Reserve (19.0%) antibiotics without a prescription, remains a significant public health issue in Pakistan [30]. In addition, there is a need to develop and introduce a national EML for Pakistan, based on the current resistance patterns observed within the country. This EML should prioritize antibiotics that are effective against locally prevalent resistant infections, ensuring a more targeted and rational approach to antimicrobial use.

Our study also highlighted that among the antibiotics on the WHO Essential Medicines List, six have no registered brands in Pakistan. This was similar to another study in Pakistan which found that 18 of these antibiotics have never been available, five have been unavailable for five years or more, and 14 have never been reported [57]. This also needs addressing going forward.

Other suggestions for the future to improve future prescribing and dispensing of antibiotics, including those from the WHO Watch and Reserve lists, includes the mandatory training of all healthcare professionals surrounding the AWaRe classification and guidance starting in Universities and continuing post qualification [41,70]. Additionally, targeted educational campaigns should be introduced to reduce patient requests for antibiotics, particularly for self-limiting infections including coughs, colds, influenza, and acute diarrhea [41,70]. In addition, reduce concerns with antibiotics dispensed by their INN name as opposed to branded generics.

This is particularly important since according to the WHO, and more recently the United Nations, at least 70% of all prescribed antibiotics should belong to the Access group [25]. Adopting and adhering to the WHO AWaRe framework and guidance will promote antimicrobial stewardship (AMS), thereby reducing inappropriate use of antibiotics [94] [21,74–76]. In addition, real-time monitoring of prescribing and dispensing practices should be introduced for both prescribers and community pharmacies as part of ASPs [70,77]. Efforts should also focus on strengthening surveillance systems and supporting research into new antibiotics and alternative treatments.

We are aware of a number of limitations with our study. First, it relied on data from the DRAP and the Pharmaguide, which may not fully represent the antibiotic market, especially regarding unregistered products. Our quantitative approach also limited qualitative insights from HCWs and patients about their experiences with antibiotic use and AMR awareness. Additionally, the data reflects a specific time period, potentially missing rapid changes in market dynamics. However, we believe our findings are robust, providing future direction to all key stakeholders in Pakistan and beyond.

## 4. Conclusion

This study highlights the concerning dynamics of the antibiotic market in Pakistan, characterized by an appreciable presence of branded generics, particularly within the WHO Watch category. The significant number of registered brands and presentations raises considerable concerns about potential overuse and misuse of antibiotics in Pakistan, which contribute to the growing threat of AMR in the country. Despite efforts including the National Action Plan on AMR, challenges persist in regulatory oversight, education, and public awareness in Pakistan. To combat AMR effectively, it is crucial to strengthen ASPs, enhance training for all HCWs, and enforce stricter regulations regarding registration and availability of branded generics, especially Watch antibiotics, and their dispensing including without a prescription. Collaborative efforts involving the government, HCWs, and the community are essential to ensure responsible antibiotic use and safeguard public health. The public health message should focus on the harms of AMR in Pakistan and its association with increased morbidity and mortality.

## Declaration of interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with

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Additional data are available from the corresponding authors on reasonable request. However, all material has been referenced.

## Author contributions

S. Abdullah, Z. Saleem, B. Godman, M. Sharland were involved with the conceptualization and methodology of the study; S. Abdullah, Z. Saleem, F.K. Hashmi, A. Haseeb, M.B.A. AL-Rawi and M.U. Qamar were involved with the investigation, data collation and formal analysis of the initial findings; all authors were involved with the visualization and update of the findings; S. Abdullah, Z. Saleem, B. Godman, M. Sharland were responsible for the literature review and initial draft of the paper with all authors involved with subsequent reviews and editing of the paper before submission. All authors approved the final submission and updates.

## Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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