



## Should dispensing antibiotics be with a doctor's prescription to the public? A study examining the implementation of the rules.

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### Abstract

The use of antibiotics, classified as prescription drugs, tends to increase in the community. Antibiotics obtained by the public from pharmacies or other retail outlets are often acquired without a doctor's prescription. The objective of this research is to understand the implementation of antibiotic dispensing rules in the community as a basis for generating policy implementation regulations and other related entities.

**Research Design:** Cross-sectional study with a qualitative approach. The research informants consist of key informants and ordinary informants. The informants in this study include pharmacy managers (APA), pharmaceutical owners (PSA), microbiology experts, BPOM, parasitology experts, pediatric specialist, Indonesian Pharmacists Association (IAI) professionals, Health Department office representatives and epidemiologist, during August to December 2023.

The research findings indicate that the widespread sale of antibiotics without a doctor's prescription is driven by the increasing needs of the community and is facilitated by pharmacies. The pharmacies involved are pharmaceutical owners and technical personnel for pharmaceutical services (TTK). There are currently no sanctions or penalties for violations of the rules committed by the owners of these facilities. The dispensing of antibiotics without a doctor's prescription is carried out by both TTK and PSA. The existence of a sense of competition among pharmacist toward neighboring pharmacies that provide antibiotics without a doctor's prescription also contributes to this practice.

**Keyword:** Pharmacy, Drugs Prescription, Antibiotics, Implementation

### INTRODUCTION

Antimicrobial resistance is a global threat arising from the misuse of antibiotics in both humans and animals, coupled with suboptimal infection prevention. Treatment for many infections is becoming less effective in various parts of the world due to the prevalence of resistance. The overuse of antibiotics is particularly common in low- and middle-income countries, where the per capita consumption of antibiotics is much lower than in high-income



countries. The risk of antibiotic misuse leads to antimicrobial resistance, which has significant implications for public health. This resistance is primarily attributed to inappropriate antibiotic prescribing and excessive antibiotic use.<sup>1,2</sup>

The alarming threat of antimicrobial resistance is particularly significant in the category of antibiotic resistance in bacteria due to the diminished effectiveness of antibiotics stemming from ongoing trends in antibiotic resistance. Antibiotic resistance jeopardizes the immune system's capacity to combat infectious diseases in humans and also contributes to various complications in vulnerable patients undergoing chemotherapy, dialysis, surgery, and joint replacement.<sup>3,4</sup>

One of the most well-known cases of antibiotic resistance is Methicillin-resistant *Staphylococcus aureus* (MRSA), associated with high mortality rates worldwide each year. Additionally, gram-negative bacteria resistant to multiple drugs (MDR-GNB) have made the treatment of various infections, such as pneumonia and urinary tract infections, more challenging.<sup>5-7</sup>

The diverse nature of antimicrobial resistance highlights the importance of understanding antibiotic consumption as a driver of resistance evolution. The variation in global antimicrobial resistance data across different countries provides an opportunity to estimate variations in antimicrobial resistance rates.<sup>2,8,9</sup> Bacteria resistant to multiple drugs in developing countries have been shown to spread rapidly, making antimicrobial resistance a recognized One Health issue.<sup>10,11</sup>

Consumption data indicates a wide variation both intra- and inter-regionally in the total amount and choice of antibiotics consumed. Overall antibiotic consumption ranges from 4.4 to 64.4 Defined Daily Doses (DDD) per 1000 population per day. In most countries, amoxicillin and amoxicillin/clavulanate are the most frequently consumed antibiotics. Antibiotic resistance has significant impacts on morbidity, mortality, and substantial economic consequences. The World Health Organization (WHO) has warned that the global antibiotic supply is at risk of depletion as the antibiotics currently in clinical practice are typically derived from modifications and short-impact cycles.<sup>12-14</sup> Infections due to antibiotic resistance lead to severe illnesses, prolonged hospitalizations, increased healthcare costs, higher second-line drug expenses, and treatment failures.<sup>3,13</sup>

The misuse of antibiotics can be attributed to the low public knowledge about the rational use of antibiotics, inadequate supervision by the authorities, disregard for medical decisions given with prescriptions, and commercialization factors. The aim of this research is to understand the implementation of rules regarding antibiotic dispensing in the community as a basis for generating policies on regulation implementation by supervisors, regulators, and professional organizations for pharmacies and other relevant entities. Therefore, this study is highly necessary to address the issues mentioned above.

## METHODE

This study used a cross-sectional design with a qualitative approach. The sources of information in this research include 23 individuals consisting of key informants and regular informants. Key informants include experts in microbiology, pharmacology, the professional organization IAI,



BPOM, parasitology experts, the city of health department, the provincial health department, and epidemiologists. Regular informants consist of 15 pharmacy managers (APA). Data collection is conducted through semi-structured individual interviews, recorded, transcribed, and analyzed based on the conventional content analysis approach. The analysis involves five steps: dividing into units of meaning, condensing units of meaning, coding, generating subcategories and categories, and forming themes, held in Palembang during August to Dec 2023. This study was approved by the ethical review committee of the Faculty of Public Health Sriwijaya University with reference number : 280/UN9.FKM/TU.KKE/2023

## RESULTS

**Table 1.** Characteristics of Respondent Demographics

Respondent Code	Sex M:Male F:Female	Age ( Years)	Educational Level	Work Experience (Years)	Position
A1 ATN1 DMP	M	45	S2	5	PSA
A2 ATN2	M	43	S2	5	APA
A3 ATN 3	F	45	S2	5	APA
A4 ATN 4	F	48	S2	6	PSA
A5 ATN 5 KF	F	40	S2	4	APA
A6 TIA 1	F	41	S1	4	APA
A7 TIA 2	M	35	S1	5	APA
A8 TIA3	M	36	S1	7	APA
A9 TIA4	F	35	S1	5	APA
A10 TIA 5	F	35	S1	5	PSA
A11 SON 1 CL	M	32	S1	4	PSA
A12 SON 2 GR	F	30	S2	5	APA
A13 SON 3 CT	F	28	S2	7	APA
A14 SON 4 M	F	45	S3	8	PSA
A15 SON 5 HM	M	50	S2	20	PSA
A16 SL 1 EL	F	38	S1	15	PSA
P 1 IAI	M	50	S2	15	Head of IAI
P2 POM	M	58	S2	20	Head of POM
P3 Farmakolog	M	55	S3	20	Expert
P4 SP MIKRO	F	54	S2	10	Expert
P5 DINKES KOTA	F	52	S2	15	Civil Servant
P6 DINKES PROV	M	54	S2	8	Civil Servant
P7 AH PAR	M	65	S3	25	Expert
P8 AH EP	M	45	S3	5	Expert
P9 RS	F	50	S2	10	IFRS
P10 AH SPA	M	58	SPA	20	Pediatric Specialist

Abbreviation :PSA Pharmaceutics Facility Owner ; APA-Pharmacist Responsibility in drugstore

**Table 2.** The implementation of rules in dispensing antibiotics with a doctor's prescription to the public



Theme	Category	Subcategory
The provisions for dispensing antibiotics	The Implementation of Government Regulations	The Challenges in Implementing Government Regulations Rewards and Penalties for Violating Regulations in the Field
The usefulness of antibiotics	The use of antibiotics with a doctor's prescription and without a doctor's prescription	Impacts of the circulation of antibiotics in society without a doctor's prescription. The number of antibiotics prescribed by doctors every day. The number of antibiotics circulating without a doctor's prescription every day. The types of antibiotics in circulation

### 1. Antibiotics Dispensation Regulation

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The statement emphasizes the importance of preserving the functionality of antibiotics, considering them as assets for humanity to combat bacteria. The concern expressed is that if we do not continuously preserve their effectiveness, there is a risk that future generations may not be able to benefit from the therapeutic effects of antibiotics. This perspective is shared by the Department of Health (Dinkes) and the National Agency of Drug and Food Control (BPOM).

2. Suggestions and strengthening measures for the sale of prescription drugs, especially those categorized as hard drugs, should be communicated to regulatory bodies and authorities such as the National Agency of Drug and Food Control (BPOM) and the Department of Health (Dinkes). Addressing the concerns of Pharmaceutical Care Providers (PSA) as a consequence of policies is crucial. The types of antibiotics that are more commonly circulated “Amoksilin and sefadroksil” (A, ), Antibiotics classified as prescription-only by medication (A, AH, P), P10AH spA

3. The usefulness of antibiotics and the types that circulating in society

The misuse and overuse of antibiotics must be halted to prevent the emergence of antibiotic-resistant bacteria. The Indonesian Pharmacists Association (IAI) emphasizes the importance of raising awareness about the dangers of antibiotic-resistant bacteria. Indiscriminate use of antibiotics without following doctor's recommendations leads to the development of bacterial



resistance. Bacteria continually adapt and evolve to survive exposure to antibiotics, employing various mechanisms to render antibiotics ineffective.

According to experts in microbiology, pharmacology, and pediatrics, the overconsumption of antibiotics and their inappropriate use, such as incorrect dosages and indications, contribute to the emergence of antibiotic-resistant bacteria. This underscores the importance of responsible antibiotic use to preserve the efficacy of these medications and avoid potential harm to the body's microbial balance. Addressing these issues requires a collaborative effort from healthcare professionals and public awareness initiatives.

"If the use of antibiotics is not for indications of infection, it will lead to bacteria being increasingly exposed to antibiotics, causing the bacteria that should be protecting us to die instead, and the bacteria resistant to this drug will freely multiply." (Opinion from Pharmacology and Microbiology Experts)

The importance of obtaining the correct diagnosis before taking antibiotics is wise because each medication has specific uses against certain bacteria. Furthermore, the use of antibiotics in non-medical sectors, such as growth promoters in farming, should also be a concern for the government in order to reduce their usage. If these antibiotics are not necessary for us to use, they should not be used because it will be harmful and have an impact on our bodies (Experts and BPOM).

4. The dispensing of antibiotics is defined as upon receiving a written request from a doctor or dentist through formal printed communication that is officially written by a licensed practicing doctor addressed to the pharmacist at the pharmacy as the provider of medications at their facility. The order for dispensing the medication is clear with the name of the medication, strength, quantity, dosage, and instructions for use.

5. The doctor has the ability and authority to conduct anamnesis and diagnosis, thus being able to prescribe the type of antibiotic based on medical necessity within the therapy. For hospitals, the regulations are very clear, in accordance with PMK numbering 8, stating that a doctor prescribing antibiotics to patients must adhere to existing regulations. Additionally, hospital accreditation, whether government or private hospitals, has been made an assessment item by considering how antibiotic use is wisely conducted by the hospital. Therefore, the control of antibiotic use in hospitals has been carried out in accordance with PMK number 8. Specifically, the use of antibiotics has been categorized into three categories as follows: 1. Antibiotics that can be prescribed by all doctors. 2. Antibiotics that require approval from the Hospital Therapeutics Committee (PGA). 3. Antibiotics that must be approved by the Hospital Infection Control Committee (PPRA). Unlike hospitals, the control of antibiotic use in pharmacies outside the hospital setting is not as stringent "(Organization of Hospital Seminar Associations)"

## **DISCUSSION**



Research findings allow us to understand the reality of antibiotic circulation in society, whether it complies with government regulations or not. The results of this research provide information regarding the circulation of antibiotics in society, indicating that there is still a need for supervision and knowledge about antibiotic circulation among the public. The main reason for dispensing antibiotics as prescription-only medication without a doctor's prescription is due to public demand, with the assumption that the public is knowledgeable about the use and dosage of antibiotic therapy. All instances of error in this phenomenon are attributed to users without any sense of responsibility from the provider of the medication. It's important to note that the errors occurring in pharmacy service activities are legally the responsibility of the pharmacist. The pharmacist, as the responsible party for pharmacy activities, is not always fully present during pharmacy opening hours, resulting in overall activities being inadequately monitored. Specifically, there is no monthly report on the use of oral antibiotics, whether with or without a doctor's prescription. This reluctance from pharmacists to discuss it with pharmacy owners is due to various reasons. The relevant parties have not been able to formulate how the implementation of Government Regulation No. 51 should be carried out comprehensively. From research results, it is known that antibiotics used for human health contribute the majority of total antibiotic consumption in society.<sup>15</sup>

In non-clinical settings, the high volume of antibiotic consumption is mostly due to easy access to antibiotics sold "somewhat freely" and the use of antibiotics without a doctor's prescription. Research by Asa et al. reveals that the sale of antibiotics without a prescription in community pharmacies globally ranges from 62% to 78%. Self-medication with antibiotics is also widely reported, with proportions in Asia showing that 58% of antibiotic usage is done without a doctor's prescription, and in Africa, 76% of antibiotics are obtained from community pharmacies without a doctor's prescription..<sup>16,17</sup>

The consistent understanding is that the use of antibiotics without a doctor's prescription poses risks to health. There needs to be an increase in awareness that there are specific regulations for the sale of antibiotics in pharmacies. Therefore, it's necessary to access healthcare services or consult a general practitioner before obtaining antibiotics. Understanding the regulations and the frequency of antibiotic use is crucial. In Indonesia, the use of antibiotics is regulated by the Minister of Health Regulation of the Republic of Indonesia Number 28 of 2021.<sup>19</sup>

There is a desire from various parties for certain antibiotics to be dispensed without a doctor's prescription by pharmacists at pharmacies, but this remains far from realization (P1). Expert opinions (AH and OP) have clearly stated that pharmacists do not conduct diagnoses or anamnesis and are not authorized to diagnose patients who come to the pharmacy. Therefore, dispensing antibiotics to patients without a doctor's prescription is a violation (P9RS)

The findings of this research also reveal the need for understanding among antibiotic providers and strengthening training for pharmacists according to their authority and expertise, which remains unmet personally. As long as healthcare workers can continue to provide effective treatment to patients with antibiotics, antibiotic resistance remains a long-term problem that does not pose a direct risk. This is in line with Ravi et al., suggesting that healthcare facilities such as hospitals need to take the initiative to rationalize antibiotic use and change prescribing behavior.<sup>20</sup> Information indicates that the perception of vulnerability to the risk of antibiotic resistance is still low among some healthcare workers and they may not understand it, leading to a tendency to overlook it.<sup>21,22</sup>



This issue is one of the contributing factors to the occurrence of resistance, thus efforts are needed to address the risk of increasing resistance through restricting antibiotic prescribing in hospitals. Focusing on infection control is considered by some as a faster and more effective solution in combating resistance, given the importance of infection control in reducing the spread of resistant bacteria.<sup>23</sup>

Changes in behavior and better knowledge among pharmacy staff and healthcare workers regarding antibiotic resistance are crucial. Prescription practices can contribute to antibiotic resistance even though it may not be directly causal.<sup>24</sup>

## **CONCLUSION**

The dispensing of antibiotics as prescription-only medication by pharmacies is driven by market demand, responding to the business world's need for sustainable pharmacy management. The continued sale of antibiotics without a doctor's prescription persists due to insufficient supervision, oversight, and sanctions. There are three key parties that require serious attention in antibiotic dispensing: the Technical Personnel for Pharmaceutical Services (TTK), the Owner of Pharmaceutic (PSA), and the Pharmacist Drugs Responsibility (APA). In addition to continuous education efforts, there is a need for new breakthroughs to address challenges and control antibiotic use. One potential solution is the issuance of directives from relevant authorities stipulating that pharmacies must only dispense prescription-only medication to the public

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## **AUTHORS CONTRIBUTION**

Sonlimar Mangunsong<sup>1</sup>, Principle Investigator, Design Research Concept, Writing Manuscript  
Sarmalina Simamora<sup>2</sup>, Writing qualitative question and collecting Data, References  
Erwin Edyansyah<sup>3</sup>, Document support  
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Rico Januar Sitorus<sup>6</sup>, Data Analysis, Interpretation, writing ethics proposed, Manuscript Draft  
Irsan Saleh,<sup>7</sup> Pharmacology References Support  
Eriza,<sup>8</sup> Microbiology References Support

## **CONFLICT of INTEREST**

**The authors declared no conflict of interest in the manuscript**

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