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# The Role of Legal Advocacy in Controlling Non-Prescription Antibiotic Use in Indonesia

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#### **Abstract**

The provision of antibiotics without doctor's prescription is serious problem in the Indonesian health system, which has impact on increasing antimicrobial resistance (AMR). Although regulations related to antibiotic use have been implemented, there are still gaps between the rules and implementation in the field. This study uses empirical legal method to analyze the effectiveness of controlling the use of antibiotics without doctor's prescription, challenges in its supervision, and strategies that can be applied to limit this practice. The results of the study show that although various regulations have strictly regulated the distribution of antibiotics, the level of pharmacy compliance with these rules is still low. A study conducted by the

Indonesian Pharmacists Association (IAI) in 2023 showed that 79.5% of pharmacies still serve the purchase of antibiotics without a prescription, with a dominance in urban areas (82.3%) compared to rural areas (71.8%). The main factors causing this violation are weak supervision, legal sanctions that are not sufficiently deterrent, and high demand from the community. In addition, the lack of health education contributes to misuse of antibiotics, which risks increasing bacterial resistance and economic burden on the health system. Strengthening supervision and law enforcement of antibiotic distribution, implementing an electronic system for recording prescriptions, and educational campaigns for community and pharmacists are needed. With a stricter and more synergistic control strategy, practice of prescribing antibiotics without prescription can be minimized, so that the risk of antimicrobial resistance can be suppressed and effectiveness of treatment can be maintained.

# **Keywords**

Antibiotics, Control, Regulation, Antimicrobial Resistance, Public Education

#### A. Introduction

Health is one of the parameters for measuring the success of human development. Without health, humans will not be productive to live economically and undergo good education. Health as one of the elements of general welfare must be realized in accordance with the ideals of the Indonesian nation as referred to in the Preamble to the 1945 Constitution through sustainable national development based on Pancasila and the 1945 Constitution. In health services, drugs are a very important component because they are needed in most health efforts<sup>2</sup>.

Ana Daniela Batista et al., "Antibiotic Dispensation without a Prescription Worldwide: A Systematic Review," *Antibiotics* 9, no. 786 (2020): 1–49.

<sup>&</sup>lt;sup>2</sup> Alian A Alrasheedy et al., "Expert Review of Anti-Infective Therapy The Impact of Law Enforcement on Dispensing Antibiotics without Prescription: A Multi-Methods Study from Saudi Arabia," Expert Review of Anti-Infective Therapy, 2019, 1–12, https://doi.org/10.1080/14787210.2020.1705156.

Antibiotics are one of the groups of drugs, both natural and synthetic, which have the effect of killing or inhibiting the growth of bacteria and each antibiotic varies greatly in its effectiveness in fighting various types of bacteria<sup>3</sup>. Antibiotics are included in the type of hard drugs whose use must be based on a doctor's prescription. This is intended so that their use is rational, with indicators of proper treatment, proper dosage, proper method of use, and proper duration of use<sup>4</sup>. Antibiotics are used to prevent and treat infectious diseases caused by bacteria<sup>5</sup>. Infectious diseases are the leading cause of death in children and young adults in the world. Infectious diseases cause more than 13 million deaths per year in developing countries including Indonesia6.

Prescribing antibiotics without a doctor's prescription is a complex problem in the Indonesian health system. This practice not only violates regulations but also increases the risk of antimicrobial resistance (AMR), which is a global threat, including in Indonesia. The World Health Organization (WHO) has designated antimicrobial resistance as one of the biggest health threats that must be addressed immediately, given its impact on the effectiveness of treatment and the increasing burden of disease in society7. In recent years, the use of antibiotics has increased significantly, both among the general public and in medical practice. Although antibiotics play an important role in treating bacterial infections, misuse and inappropriate use can lead to various health problems, including

Narmeen Mallah et al.. "Education Level and Misuse of Antibiotics in the General Population: A Systematic Review and Dose-Response Meta-Analysis," Antimicrobial Resistance and Infection Control 11, no. 1 (2022): 1-22, https://doi.org/10.1186/s13756-022-01063-5.

<sup>&</sup>lt;sup>4</sup> Marina Fuertes et al., "Antibiotic Consumption, Illness, and Maternal Sensitivity in Infants with a Disorganized Attachment," Children 10, no. 7 (2023): 1-14, https://doi.org/10.3390/children10071232.

<sup>&</sup>lt;sup>5</sup> Pendo M Ndaki et al., "Dispensing Antibiotics without Prescription at Community Pharmacies and Accredited Drug Dispensing Outlets in Tanzania: A Cross-Sectional Study," *Antibiotics* 10, no. 1025 (2021): 1–15.

Badan Pengawas Obat dan Makanan (Badan POM), Pedoman Penggunaan Antibiotik di Indonesia (Jakarta: Badan POM, 2011).

Miguel Servia-dopazo and Adolfo Figueiras, "Determinants of Antibiotic Dispensing without Prescription: A Systematic Review," Journal of Antimicrobial Chemotherapy 73 (2018): 3244-53. https://doi.org/10.1093/jac/dky319.

antibiotic resistance. Antibiotic resistance is a condition in which bacteria become immune to the effects of antibiotics, making treatment of infections increasingly difficult and risky. According to data from the World Health Organization (WHO), antibiotic resistance is estimated to cause 10 million deaths per year worldwide by 2050 if no action is taken to address this problem. In Indonesia, prescribing antibiotics without a prescription is a practice that is still often found, even though existing regulations have expressly stated that the use of antibiotics must be based on medical recommendations<sup>8</sup>.

Regulations related to antibiotic use in Indonesia are regulated in various laws and regulations, including Law Number 36 of 2009 concerning Health, Government Regulation Number 51 of 2009 concerning Pharmaceutical Work, Minister of Health Regulation Number 35 of 2014 concerning Pharmaceutical Service Standards in Pharmacies, and Minister of Health Regulation (Permenkes) Number 28 of 2021 concerning Guidelines for Antibiotic Use. These regulations emphasize that antibiotics are included in the category of hard drugs that may only be given with an original doctor's prescription with a validity period of 30 days9. In Minister of Health Regulation Number 35 of 2014, it is stated that one of the duties of a pharmacist is clinical pharmacy services which include drug information services and patient counseling<sup>10</sup>. However, this new regulation does not make the use of antibiotics legal, although pharmacists can provide antibiotic drug information services or counseling regarding antibiotic use. This is because, according to the regulations on antibiotics, to get antibiotics you must have a doctor's prescription. Therefore, counseling for patients in the form of using antibiotics without a doctor's prescription is basically limited to providing advice to direct patients to see a doctor and providing an explanation of the advantages and disadvantages of inappropriate antibiotic use. Because, if the pharmacist chooses antibiotics, it will violate the Law on the

World Health Organization, No Time to Wait: Securing the Future from Drug-Resistant Infections (WHO, 2019).

<sup>&</sup>lt;sup>9</sup> Kementerian Kesehatan Republik Indonesia, *Peraturan Menteri Kesehatan Nomor 28 Tahun 2021 tentang Pedoman Penggunaan Antibiotik*, (2021).

Kementerian Kesehatan Republik Indonesia, Peraturan Menteri Kesehatan Nomor 35 Tahun 2014 tentang Standar Pelayanan Kefarmasian di Apotek, (2014).

distribution of antibiotics<sup>11</sup>. However, in practice, there are still many pharmacies that provide antibiotics to patients without a valid prescription, indicating a gap between regulation and implementation in the field.

Data from the World Health Organization (WHO) in 2024 recorded Indonesia as the country with the third highest level of antimicrobial resistance in Southeast Asia, with 58% of common bacterial infection cases already showing resistance to first-line antibiotics<sup>12</sup>. This phenomenon is inseparable from the rampant over the counter sales of antibiotics which reached 2.3 million packages per month according to the 2023 BPOM audit<sup>13</sup>. Ironically, this situation is contrary to the regulatory framework which has actually classified antibiotics as hard drugs that require a doctor's prescription based on Permenkes No. 35/2014 in conjunction with Permenkes No. 28/2021. The results of a cross-sectional study by the Indonesian Pharmacists Association (IAI) on 2,400 pharmacies in 12 provinces (2023) revealed the fact that 79.5% of pharmacies still serve requests for antibiotics without a prescription, with the largest distribution pattern in urban areas (82.3%) compared to rural areas (71.8%). Amoxicillin was the most frequently misused antibiotic (36.2% of cases), cefadroxil (24.1%) and ciprofloxacin (18.7%)<sup>14</sup>.

This can be caused by various factors, including weak supervision, lack of pharmacist compliance with regulations, and high demand from the public who do not understand the dangers of using antibiotics inappropriately, low law enforcement, and a culture that considers antibiotics as a quick solution to various health problems<sup>15</sup>. Despite having a strong legal umbrella, policy implementation is hampered by three critical factors, including

<sup>&</sup>lt;sup>11</sup> Edi Widayat, "Perlindungan Hukum Pasien Terhadap Pemberian Obat Yang Tidak Rasional Dalam Upaya Keselamatan Pasien," Jurnal Spektrum Hukum 14, no. 2 (2017): 250-64.

<sup>&</sup>lt;sup>12</sup> World Health Organization, *Antimicrobial Resistance in Southeast Asia:* Regional Report (WHO, 2024)

<sup>&</sup>lt;sup>13</sup> Badan Pengawas Obat dan Makanan (BPOM), Laporan Audit Distribusi Antibiotik di Indonesia (BPOM, 2023)

<sup>&</sup>lt;sup>14</sup> Ikatan Apoteker Indonesia, Laporan Studi Cross-Sectional tentang Distribusi Antibiotik di Apotek (IAI, 2023).

<sup>&</sup>lt;sup>15</sup> Ni Komang, Novita Dewi, and Debby Juliadi, "Faktor Penyebab Perilaku Penjualan Dan Pembelian Antibiotik Tanpa Resep Dokter: Studi Literatur," Jurnal Farmasi & Sains Indonesia 4, no. 2 (2021): 19–25, https://doi.org/10.52216/jfsi.vol4no2p19-25.

administrative sanctions in Permenkes No. 8/2015 concerning PPRA only in the form of written warnings to a maximum fine of IDR 50 million which is not comparable to the economic benefits of illegal sales, a manual reporting mechanism that relies on public reports while 87% of patients are not aware of violations.

public reports while 87% of patients are not aware of violations according to a 2023 Ministry of Health survey, and the conflict between the role of pharmacists as health workers vs. the demands of pharmaceutical business profits<sup>16</sup>.

One of the main impacts of prescribing antibiotics without a prescription is the increase in bacterial resistance to antibiotics. This resistance can cause infections that are more difficult to treat, increase morbidity and mortality rates, and burden the health system with increased treatment costs due to the need to use more expensive and more toxic second or third line antibiotics<sup>17</sup>. In addition, antibiotic misuse also has an impact on the effectiveness of treating various infectious diseases, such as respiratory tract infections, urinary tract infections, and skin diseases, which can ultimately reduce the overall quality of life of the community. This condition is exacerbated by the lack of adequate education and information regarding the correct use of antibiotics. Many people still assume that antibiotics can be used to treat all types of infections, including viral infections, which actually do not require antibiotic treatment. In addition, easy access to antibiotics in pharmacies without a doctor's prescription is also a driving factor for misuse. In many cases, pharmacists provide antibiotics to patients without conducting adequate examinations, increasing the risk of inappropriate use<sup>18</sup>.

From a legal perspective, there is still a gap between existing regulations and implementation in the field. Although there are regulations governing the distribution and use of antibiotics,

Putri Mahirah Afladhanti, Arya Marganda Simanjuntak, and Yohanes Firmansyah, "Tinjauan Hukum Penjualan Antibiotik Tanpa Resep Dokter Pada Era E - Commerce Di Indonesia," Kongres Ke-6 MHKI: Presented Masyarakat Hukum Kesehatan Indonesia, 2024, 328–43.

Ndaki et al., "Dispensing Antibiotics without Prescription at Community Pharmacies and Accredited Drug Dispensing Outlets in Tanzania: A Cross-Sectional Study."

Alrasheedy et al., "Expert Review of Anti-Infective Therapy The Impact of Law Enforcement on Dispensing Antibiotics without Prescription: A Multi-Methods Study from Saudi Arabia."

violations of these regulations still often occur without strict legal consequences. The lack of law enforcement against pharmacies that violate the rules is one of the main reasons why the practice of providing antibiotics without a prescription still occurs<sup>19</sup>. The lack of supervision from authorities, such as the Food and Drug Supervisory Agency (BPOM) and the Health Service, causes many pharmacies to violate the rules without being sanctioned. This shows the need for stricter control over the practice of providing antibiotics without a doctor's prescription, both through more intensive supervision and increasing pharmacist compliance with applicable regulations.

In addition to regulatory and law enforcement aspects. social and economic factors also play a role in the rampant provision of antibiotics without a prescription. Many people consider antibiotics as drugs that can be used for various types of diseases without understanding the proper medical indications. The lack of health education and public awareness of the dangers of antibiotic resistance also encourages this practice to continue. On the other hand, business competition between pharmacies and economic pressures can be factors that cause some pharmacists to ignore regulations in order to increase profits. Without strict supervision and adequate education, this practice will continue and contribute to wider health problems<sup>20</sup>.

Efforts to suppress the practice of prescribing antibiotics without a prescription require a holistic approach, including strengthening policies, stricter supervision, and educating the public about the dangers of antibiotic misuse. The government must ensure that the regulations that have been set can be implemented effectively by involving various parties, including health workers, educational institutions, and law enforcement agencies. In addition, the use of technology such as electronic systems in recording and monitoring prescriptions can be a

<sup>19</sup> Servia-dopazo and Figueiras, "Determinants of Antibiotic Dispensing without Prescription: A Systematic Review."

<sup>&</sup>lt;sup>20</sup> Suzanalisa and Nuraini Zachman, "Pertanggungjawaban Pidana Terhadappelaku Tindak Pidana Mengedarkan Obat Tanpa Izin Edar Suzanalisa," Legalitas: Jurnal Hukum 14, no. 1 (2022): 146-55, https://doi.org/10.33087/legalitas.v14i1.323.

solution to increase transparency and accountability in prescribing antibiotics<sup>21</sup>.

Based on this background, research on controlling the use of antibiotics without a doctor's prescription is very important. This study aims to analyze the regulations governing the control of the use of antibiotics without a doctor's prescription in Indonesia, identify challenges in controlling the practice, and evaluate the effectiveness of the policies that have been implemented. In addition, this study will provide strategic recommendations to strengthen supervision. compliance with regulations, and prevent antibiotic misuse by the public and pharmacists. By understanding the obstacles in these control efforts, it is hoped that more comprehensive solutions can be implemented to minimize the risk of antimicrobial resistance and ensure more responsible antibiotic use in Indonesia.

This study uses an empirical legal method<sup>22</sup>, which aims to analyze efforts to control the use of antibiotics without a doctor's prescription through applicable regulations and the implementation of various monitoring mechanisms. This approach is used to examine the extent to which control policies have been implemented, identify strategies that have been carried out by related parties, and evaluate challenges in enforcing regulations to limit antibiotic misuse.

The data used in this study consists of primary, secondary and tertiary data. Primary data in the form of laws and regulations directly related to the regulation of antibiotic use, including:

- 1) Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia, which guarantees the right of every person to obtain health services,
- 2) Law Number 36 of 2009 concerning Health, which regulates drugs and pharmaceutical distribution.

Adeel Aslam et al., "Understanding the Determinants Influencing Self-Medication with Antibiotics Among Malaysian Residents: A Qualitative Study to Inform Preventive Public Health Strategies," Antibiotics 13, no. 11 (2024): 1–19, https://doi.org/10.3390/antibiotics13111070.

<sup>&</sup>lt;sup>22</sup> Achmad Ali, *Menjelajahi Kajian Empiris Terhadap Hukum* (Jakarta: Kencana, 2012), pp. 21-29.

- 3) Government Regulation Number 51 of 2009 concerning Pharmaceutical Work, which regulates the authority and responsibilities of pharmacists in providing pharmaceutical services.
- 4) Minister of Health Regulation Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies, which sets standards in pharmaceutical services including distribution of prescription drugs.
- 5) Regulation of the Minister of Health Number 28 of 2021 concerning Guidelines for the Use of Antibiotics, which is the basis for controlling the distribution of antibiotics to prevent antimicrobial resistance.

Secondary data were obtained through field observations of the number of cases of antibiotic use without a doctor's prescription in Indonesia and the extent to which control efforts have been carried out. These observations include the level of pharmacy compliance in requesting a prescription before providing antibiotics, cases of violations of antibiotic distribution without a prescription that still occur, and steps taken by the authorities to suppress such misuse. In addition, observations were also made on the effectiveness of supervision by related institutions, such as the Ministry of Health, the Food and Drug Supervisory Agency (BPOM), and Health Services in various regions in dealing with cases of antibiotic misuse. While dtertiary or obtained through literature studies of various academic references, including scientific journals, policy reports, and research documents discussing antibiotic control strategies in various countries.

Data analysis was conducted using a descriptive-analytical approach, which aims to systematically describe the control strategies that have been implemented, evaluate their effectiveness, and identify weaknesses in the implementation of regulations. With this method, this study is expected to provide more concrete recommendations in strengthening efforts to control antibiotic distribution, increasing the effectiveness of supervision, and improving existing policies to prevent antibiotic misuse in Indonesia.

# B. Analysis of Antibiotic Use Regulation in Indonesia

Medicine is the main commodity used by humans to support their health. Everyone is willing to spend their money to get health, even some say "health is expensive"<sup>23</sup>. The development of the increasingly sophisticated era like today, there are many kinds of food that will later have an impact on our health, for that medicine is very necessary in our lives. Medicine is so important in human life that in its manufacture, medicine must meet the criteria of efficacy, safety, and quality. These criteria must be met starting from the manufacture, distribution to the delivery of medicine to the hands of consumers so that the quality of the medicine is maintained until the medicine is finally consumed by the patient<sup>24</sup>.

The government has created a guideline for the pharmaceutical industry, commonly called Good Manufacturing Practices (GMP) so that drugs can meet the three drug criteria mentioned above. The provisions contained in GMP are certainly very strict in order to create a drug that truly meets the criteria of efficacy, safety, and quality. Strict regulations during the drug manufacturing process will be in vain if there is an error in the distribution of the drug that reduces the quality of the drug or can even produce a toxic product that can actually endanger patient safety.

One group of drugs that are often misused and distributed without strict supervision is antibiotics. Antibiotics are a type of drug used to treat bacterial infections, but uncontrolled use can have negative impacts, such as antimicrobial resistance. This resistance occurs when bacteria become immune to the effects of antibiotics, so that infections that were previously easy to treat become difficult to cure<sup>25</sup>. Misuse of antibiotics without a

Ndaki et al., "Dispensing Antibiotics without Prescription at Community Pharmacies and Accredited Drug Dispensing Outlets in Tanzania: A Cross-Sectional Study."

Dewi Paskalia Andi Djawaria, Adji Prayitno Setiadi, and Eko Setiawan, "Pengembangan Kuesioner Dan Identifikasi Faktor Penyebab Penjualan Antibiotik Tanpa Resep Dokter Di Komunitas Kota Surabaya," *Jurnal Manajemen Dan Pelayanan Farmasi* 8, no. 3 (2018): 105–18, http://repository.ubaya.ac.id/id/eprint/34134.

Hubertus Veron Mailuhuw, Theresia Louize Pesulima, and Yosia Hetharie, "Perlindungan Konsumen Terhadap Penjualan Obat Antibiotik Tanpa Resep Dokter," *Pattimura Law Study Review* 1, no. 1 (2023): 336–46.

doctor's prescription, either due to a lack of public understanding or weak supervision in pharmacies, further exacerbates this condition26. Therefore, control of antibiotic distribution must be tightened to ensure that their use is in accordance with medical needs and prevent adverse impacts on public health.

Regulations related to the provision of antibiotics in Indonesia are regulated through various laws and regulations aimed at ensuring the rational use of antibiotics and preventing antimicrobial resistance. Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia emphasizes that every citizen has the right to receive optimal health services, including in terms of the use of safe medicines and in accordance with medical procedures. Law Number 36 of 2009 concerning Health provides the legal basis for drug distribution and pharmaceutical circulation in Indonesia. This regulation stipulates that prescription drugs, including antibiotics, may only be given based on a doctor's prescription to ensure that their use is in accordance with a proper medical diagnosis. Article 98 paragraph (2) states that drugs are materials or combinations of materials, including biological products used to influence or investigate physiological systems or pathological conditions in order to determine a diagnosis, prevention, healing, recovery, health improvement, and contraception. Meanwhile, Article 106 paragraph (1) emphasizes that drug circulation must meet safety, efficacy, and quality requirements and may only be given based on a doctor's prescription for types of drugs classified as prescription drugs, including antibiotics.

Government Regulation Number 51 of 2009 concerning Pharmaceutical Work provides provisions regarding the authority and responsibility of pharmacists in pharmaceutical services. In this regulation, pharmacists are responsible for providing drugs, providing information to patients, and ensuring that drug distribution is in accordance with applicable regulations. Article 16 states that pharmacists in carrying out their work are required to provide pharmaceutical services that include the management of pharmaceutical preparations and

<sup>&</sup>lt;sup>26</sup> Carl Llor, Ria Benkő, and Lars Bjerrum, "Global Restriction of the Over-the-Counter Sale of Antimicrobials: Does It Make Sense?," Frontiers in Public Health 12 (2024): 1-4, https://doi.org/10.3389/fpubh.2024.1412644.

clinical pharmacy services. Article 25 emphasizes that in terms of clinical pharmacy services, pharmacists are required to provide correct and clear information to patients regarding the drugs provided, including in this case regarding the use of antibiotics. Thus, providing antibiotics without a doctor's prescription is contrary to this regulation because it violates established procedures and can be subject to administrative to criminal sanctions as regulated in Article 55 which states that violations of this regulation can be subject to sanctions ranging from warnings to revocation of practice permits<sup>27</sup>.

Minister of Health Regulation Number 28 of 2021 concerning Guidelines for Antibiotic Use further clarifies that antibiotic distribution must be closely monitored to prevent antimicrobial resistance. including antibiotic restrictions and de-escalation of therapy. This regulation provides guidelines on the correct use of antibiotics, including restrictions on their distribution. Article 4 paragraph (1) emphasizes that the use of antibiotics must be in accordance with guidelines for good antibiotic use, including in terms of selecting the right antibiotic based on the results of a medical examination. Article 10 states that antibiotics can only be given with a doctor's prescription, except under certain conditions that have been determined by the Minister of Health. In addition, Minister of Health Regulation Number 73 of 2016 concerning Standards of Pharmaceutical Services in Pharmacies regulates standards in pharmaceutical services that must be adhered to by pharmacists. including the obligation to provide antibiotics only based on a doctor's prescription and accompanied bv adequate explanations of use. Article 20 paragraph (1) states that prescription services must be carried out professionally by pharmacists who are responsible for ensuring appropriateness of the indications, dosages, and possible side effects of the drugs given. Meanwhile, Article 24 emphasizes that pharmacists are required to provide counseling to patients regarding the correct use of drugs, including providing information regarding the risks of using antibiotics that do not comply with regulations.

<sup>&</sup>lt;sup>27</sup> Suzanalisa and Zachman, "Pertanggungjawaban Pidana Terhadappelaku Tindak Pidana Mengedarkan Obat Tanpa Izin Edar Suzanalisa,."

Based on the regulatory aspect, the government has established a strong legal basis to prevent antibiotic misuse. With clear regulations regarding the distribution and use of antibiotics, it is hoped that the public can better understand the importance of rational antibiotic use. In addition, compliance with this regulation is highly dependent on cooperation between the government, pharmacists, and other health workers in ensuring that antibiotics are used responsibly. Therefore, stricter efforts are needed in monitoring and socializing this regulation to all stakeholders to ensure that policies related to antibiotic use can be implemented optimally to prevent antimicrobial misuse and resistance.

# C. Evaluation of The Control of Non-Prescription Antibiotic Use in Indonesia

The existing regulations in Indonesia regarding the provision of antibiotics by pharmacists without a prescription are quite comprehensive. However, the main challenge lies in the implementation and enforcement of the law. Although the Constitution and the Health Law guarantee the right of the community to receive good health services, in reality many people do not receive adequate information regarding the correct use of antibiotics. The Minister of Health's regulation on antibiotic use guidelines has also not been fully implemented. Many pharmacists do not know or do not understand the contents of the existing regulations, so they cannot apply them in daily practice. This shows a gap between the regulations that have been set and pharmacists' understanding and awareness of these regulations. In addition, although there are clear regulations regarding pharmacists' authority, many pharmacists feel pressured to fulfill patient requests, who often ask for antibiotics without a prescription. This situation creates an ethical dilemma for pharmacists, where they must choose between complying with regulations or meeting patient expectations. As many as 93% of people in developing countries, including Indonesia. obtain antibiotics from pharmacies/drugstores—in contrast to strict Northern European countries.

The use of antibiotics without a doctor's prescription in Indonesia remains a critical public health problem. Based on data from the 2023 Indonesian Health Survey (SKI), 41% of oral antibiotics were obtained without a prescription, with the highest proportion variation in the central and eastern regions of Indonesia<sup>28</sup>. This practice accelerates the rate of antimicrobial resistance (AMR), which is projected to cause 10 million global deaths per year by 2050 if uncontrolled. Although the government has issued the General Guidelines for Antibiotic Use (2011) and the National Action Plan for Controlling Antimicrobial Resistance (RAN-PRA), its implementation faces structural challenges such as access to health services, public awareness, and regulatory enforcement.

Based on BPOM's undercover investigation in 120 pharmacies in Java-Bali (2024), five patterns of violations were identified<sup>29</sup>:

- a. Fictitious prescriptions (42% of cases): Pharmacists create dummy prescriptions under fake doctor names.
- b. Split dispensing (28%): Dividing commercial antibiotic packages into retail preparations
- c. Expired prescription (17%): Using expired prescriptions from regular patients
- d. OTC Antibiotics (9%): Display antibiotics on open shelves like over-the-counter medications
- e. Online backdoor (4%): Serving orders via digital platforms without verification

As much as 60-70% of antibiotic transactions in private pharmacies are still carried out without a prescription, especially for amoxicillin and cephalosporin groups. A cost-benefit analysis by the Eijkman Institute (2024) revealed that the profit margin for illegal antibiotics reached 30-70% compared to legal sales. For example, 500mg amoxicillin tablets which should be sold for IDR 1,500/tablet with a prescription, are sold freely for IDR 4,500-6,000/tablet. Based on field observation data, it shows that in Surabaya, 79 out of 80 pharmacies provide antibiotics without a prescription, in Tangerang, 89% of pharmacists sell antibiotics without a prescription, there are even cases of

Survei Kesehatan Indonesia, Laporan Survei Kesehatan Masyarakat Terkait Penggunaan Antibiotik Tanpa Resep (Jakarta: Kementerian Kesehatan RI, 2023)

<sup>&</sup>lt;sup>29</sup> Badan Pengawas Obat dan Makanan, *Investigasi undercover BPOM di 120 apotek Jawa-Bali* (Jakarta: BPOM, 2024)

antibiotics packaged in plastic without a label, and the Special Region of Yogyakarta recorded the lowest proportion (below 41%), while 18 other provinces exceeded the national average. The types of antibiotics that are often used without a doctor's prescription include Amoxicillin (80.56% of cases), ampicillin, tetracycline, and ciprofloxacin. Health conditions that are often treated with antibiotics are flu (25.93%), sore throat (17.59%), and diarrhea. The main reasons for their use are previous experience that is considered successful (58.33%) and cost considerations<sup>30</sup>.

Pharmacists play a very important role in controlling antibiotic use. They are at the forefront of providing information and education to patients regarding the proper use of drugs<sup>31</sup>. However, in order to carry out this role properly, pharmacists need to receive adequate training regarding antibiotic use and the impact of antibiotic resistance. Several pharmacists expressed that they felt they did not receive enough support from professional organizations in terms of training and professional development<sup>32</sup>. Therefore, it is important for professional organizations such as the Indonesian Pharmacists Association (IAI) to improve training and education programs for their members. By improving the competence of pharmacists, it is hoped that they can provide better services and comply with existing regulations. In addition, pharmacists often face ethical dilemmas when patients ask for antibiotics without a prescription. Many pharmacists feel forced to fulfill the request, even though they realize that this action violates regulations. In addition, the lack of public knowledge regarding the dangers of inappropriate antibiotic use is also a driving factor for misuse<sup>33</sup>.

<sup>30</sup> Lembaga Eijkman, Analisis Biaya-Manfaat Penggunaan Antibiotik di Indonesia (Jakarta: Lembaga Eijkman, 2024)

<sup>31</sup> MM Thandar, T Baba, S Matsuoka, dan E Ota, Interventions to Reduce Non-Prescription Antimicrobial Sales in Community Pharmacies, Cochrane Database of Systematic Reviews 2025, no. 1 (2025): Art. No. CD013722, https://doi.org/10.1002/14651858.CD013722.pub2.

<sup>32</sup> Md Sabbir Hossain et al., "Antibiotic Prescription from Qualified Sources for Children with Fever/Cough: Cross-Sectional Study from 59 Low- and Middle-Income Countries," EClinical Medicine 61, no. 113035 (2023): 1–14, https://doi.org/10.1016/j.eclinm.2023.102055.

<sup>&</sup>lt;sup>33</sup> Aurélie Bocquier et al., "Impact of a Public Commitment Charter, a Non-Prescription Pad and an Antibiotic Information Leaflet to Improve Antibiotic Prescription among General Practitioners: A Randomised

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Education should be carried out not only by pharmacists, but also by other health workers, including doctors and nurses. Information campaigns involving the mass media, schools, and communities can also help raise public awareness. By increasing public understanding of the correct use of antibiotics, it is hoped that the demand for antibiotics without a prescription can be reduced. In addition, low public awareness of the dangers of inappropriate antibiotic use contributes to antibiotic misuse<sup>34</sup>.

Controlled Study," Journal of Infection and Public Health 17, no. 2 (2024): 217–25, https://doi.org/10.1016/j.jiph.2023.11.027.

<sup>&</sup>lt;sup>34</sup> A. S. Ouedraogo et al., "Émergence et diffusion de la résistance aux antibiotiques en Afrique de l'Ouest: facteurs favorisants et évaluation de la

Many people still believe that antibiotics can be used to treat all types of infections, including viral infections, which do not actually require antibiotic treatment. This indicates the need for more intensive educational efforts to improve understanding of the rational use of antibiotics.

Ministry of Health laboratory surveillance for the period 2021-2024 shows an increase in bacterial resistance to major antibiotics35:

- Escherichia coli: Ceftriaxone resistance increases from 51% (2021) to 67% (2024)
- Staphylococcus aureus: Methicillin resistance reaches 82% b. in teaching hospitals
- Klebsiella pneumoniae: 73% of isolates were resistant to ≥3 c. classes of antibiotics

In terms of implementation, supervision of pharmacies is also still weak. BPOM and the Health Office have the responsibility to carry out supervision, but limited resources and personnel make supervision ineffective. Many pharmacies operate without adequate inspections, so violations of regulations go undetected.

Based on the empirical legal approach carried out through field observations, it can be concluded that there are several main factors that cause the use of antibiotics without a doctor's prescription in Indonesia, including:

High patient demand/lack of public awareness: many patients are accustomed to getting antibiotics without a prescription from pharmacies due to a lack of understanding about the dangers of antimicrobial resistance. Most people think that antibiotics are a quick solution for various diseases, including the common cold or cough, which actually do not always require the use of antibiotics. A study in Jakarta showed that 83.3% of pharmacists admitted to often selling antibiotics without a prescription due to market demand pressure<sup>36</sup>.

menace," Médecine et Santé Tropicales 27, no. 2 (2017): 147-154, https://doi.org/10.1684/mst.2017.0678.

<sup>35</sup> Kementerian Kesehatan RI, Laporan Surveilans Resistensi Antimikroba Periode 2021-2024 (Jakarta: Kementerian Kesehatan RI, 2024)

<sup>&</sup>lt;sup>36</sup> Llor, Benkő, and Bjerrum, "Global Restriction of the Over-the-Counter Sale of Antimicrobials: Does It Make Sense?"

- 2. Lack of supervision and law enforcement: although the regulations are clear, supervision by authorities such as BPOM and the Health Department on practices in pharmacies is still limited and weak. The lack of supervision and strict sanctions has resulted in many pharmacies still violating the rules without receiving strict legal consequences<sup>37</sup>.
- 3. Business competition in the pharmaceutical sector: pharmacies in areas with tight competition sometimes ignore regulations and continue to sell antibiotics without a prescription in order to retain customers. This is especially true in areas with many pharmacies and minimal direct government control<sup>38</sup>.
- 4. Lack of education for pharmacists and pharmaceutical workers: although pharmacists have an understanding of the regulations, there are still pharmaceutical workers who lack training on the importance of compliance with the rules in administering antibiotics. This results in practices that are contrary to applicable regulations (unable to provide accurate information to patients)<sup>39</sup>.

National programs and educational campaigns have also been implemented in Indonesia in order to control the use of antibiotics without prescriptions, covering various strategies involving a multi-sectoral approach and cross-institutional collaboration. Two major initiatives that have been implemented are the National Action Plan for Controlling Antimicrobial Resistance (RAN-PRA) 2017-2019 and the Smart Community Movement for Using Medicines (*GeMa CerMat*) 2015.

Sawsan Kurdi et al., "Assessment of Knowledge and Attitude toward the New Antibiotic Dispensing Law and Its Effect on Antibiotic Use in Saudi Arabia," Saudi Pharmaceutical Journal 28, no. 1 (2020): 58–67, https://doi.org/10.1016/j.jsps.2019.11.005.

<sup>37</sup> Hossain et al., "Antibiotic Prescription from Qualified Sources for Children with Fever/Cough: Cross-Sectional Study from 59 Low- and Middle-Income Countries."

<sup>&</sup>lt;sup>39</sup> Faten Alhomoud et al., "Self-Medication and Self-Prescription with Antibiotics in the Middle East—Do They Really Happen? A Systematic Review of the Prevalence, Possible Reasons, and Outcomes," *International Journal of Infectious Diseases* 57 (2017): 3–12, https://doi.org/10.1016/j.ijid.2017.01.014.

### 1) National Action Plan for Controlling Antimicrobial Resistance (RAN-PRA) 2017-2019

RAN-PRA adopts the One Health approach, which is a global strategy to address antimicrobial resistance (AMR) through cross-sector collaboration, including human health, animal health, the environment, and the food sector. This approach is important because antimicrobial resistance is not only triggered by the use of antibiotics in the human health sector but is also influenced by their use in livestock and agriculture. In its implementation. RAN-PRA focuses on five main pillars:

- Awareness and understanding of antimicrobial resistance through public campaigns and education of health workers.
- Surveillance and research related to AMR, including h. monitoring of bacterial resistance patterns to antibiotics in hospitals and other health facilities.
- Wiser use of antibiotics in human and animal health, by C. tightening regulations on antibiotic prescribing and distribution.
- Increasing laboratory capacity to support early detection and monitoring of antibiotic resistance cases.
- Investment in innovation and technological development, e. such as the development of alternative antibiotics and vaccination as a preventive strategy.

However, even though RAN-PRA has been running for several years, major challenges are still faced in implementation. One of the main obstacles is the low public awareness of the risk of antimicrobial resistance. For example, a study in Manggarai showed that 58.33% of patients had a low understanding of AMR, which means that many people still consider antibiotics as drugs that can be consumed without medical supervision. In addition, the lack of coordination between the human and animal health sectors is also an obstacle in ensuring the effectiveness of this policy.

## 2) Smart Community Movement for Using Medicine (GeMa CerMat) 2015

As part of efforts to increase public literacy regarding rational drug use, the Indonesian Ministry of Health launched GeMa CerMat in 2015. This program aims to:

Increasing public understanding about the rational use of drugs, including antibiotics.

- a. Strengthening the role of pharmacists in educating patients regarding the risks of using antibiotics without a prescription.
- b. Facilitating access to information about drugs through various media, including direct counseling, digital campaigns, and collaboration with educational institutions.

  GeMa CerMat has been carried out in various regions with

various forms of approach, such as:

- a. Educational campaigns in health facilities, including hospitals and pharmacies, emphasizing the importance of taking antibiotics as prescribed by a doctor.
- b. Involvement of health workers and communities, such as integrated health post cadres and community organizations, to disseminate information related to antibiotic resistance.
- c. Provision of educational materials in the form of brochures, social media, and public service announcements, which are targeted to reach the wider community.

However, even though this program has been running for almost a decade, its effectiveness is still limited due to several factors, including lack of active community participation, lack of supervision of pharmacies and health workers, and uneven distribution of information.

Although Indonesia has implemented various strategies in controlling the use of antibiotics without prescription, there are still major challenges in implementing policies and educating the public. Several factors that influence the success of this control program include:

a) Lack of strict sanctions for violators of regulations – There are still many pharmacies that sell antibiotics without a doctor's prescription without receiving strict sanctions from health authorities<sup>40</sup>.

<sup>&</sup>lt;sup>40</sup> Fauna Herawati et al., "Interview-Based Cross-Sectional Needs Assessment to Advance the Implementation of an Effective Antibiotic Stewardship Program in Indonesian Hospitals," *Health Policy OPEN* 1, no. 100002 (2020): 1–8, https://doi.org/10.1016/j.hpopen.2019.100002.

- b) Low levels of public health literacy The education provided is often not strong enough to change the behavior of people who are used to consuming antibiotics freelv<sup>41</sup>.
- c) Limited resources in policy implementation Suboptimal supervision, especially in remote areas, results in weak control of antibiotic distribution at the field level<sup>42</sup>.

A comprehensive evaluation and policy improvement are needed so that the strategies that have been implemented can run more effectively. A stricter approach in regulating antibiotic distribution, strengthening the capacity of health workers in providing education, and increasing active community participation are important steps that need to be considered in controlling the use of antibiotics without a prescription in Indonesia.

# D. Optimizing Control of Non-Prescription Antibiotic Use in Indonesia

Although Indonesia has regulations governing the use of antibiotics, the implementation of this policy still faces many obstacles. National programs such as the 2017-2019 National Action Plan for Controlling Antimicrobial Resistance (RAN-PRA), which adopts the One Health approach and involves various sectors, and the 2015 Smart Community Movement for Using Medicines (GeMa CerMat), have been implemented. However, the effectiveness of these programs is still limited due to weak implementation in the field, lack of ongoing monitoring, and low compliance of the community and health workers with existing policies.

show Observations in various regions pharmacies still sell antibiotics without a doctor's prescription. In addition, health workers in several medical facilities also often prescribe antibiotics excessively, even for diseases that do not require antibiotics. The low level of public understanding of the risk of antimicrobial resistance is also a factor that exacerbates

<sup>&</sup>lt;sup>41</sup> Darto Supadmo et al., "Penerapan Hukum Dalam Menanggulangi Penyalahgunaan Antibiotik: Tantangan, Solusi, Dan Dampak Terhadap Keamanan Kesehatan Masyarakat Di Indonesia," Jurnal Hukum Dan Kewarganegaraan 8, no. 9 (2024): 1-18.

<sup>&</sup>lt;sup>42</sup> Batista et al., "Antibiotic Dispensation without a Prescription Worldwide: A Systematic Review."

this problem. National programs such as the 2017-2019 National Action Plan for Controlling Antimicrobial Resistance (RAN-PRA). which adopts the One Health approach and involves various sectors, and the 2015 Smart Community Movement for Using Medicines (GeMa CerMat), which aims to increase public awareness, have been implemented. However, the effectiveness of these programs is still limited due to weak implementation in the field, lack of ongoing monitoring, and low compliance of the community and health workers with existing policies

In facing the challenges of antimicrobial resistance and uncontrolled antibiotic use, more effective and comprehensive strategic steps are needed. Here are some recommendations that can be implemented to optimize the control of antibiotic use in Indonesia:

#### 1) Strengthening Regulation and Law Enforcement

Regulations on the use of antibiotics have been regulated in various laws and regulations in Indonesia, but their implementation still needs to be strengthened. One of the main regulations is Law Number 36 of 2009 concerning Health, which states that prescription drugs, including antibiotics, can only be obtained with a doctor's prescription. In addition, the Regulation of the Minister of Health (Permenkes) Number 35 of 2014 concerning Pharmaceutical Service Standards in Pharmacies states that pharmacists are required to ensure that the drugs given to patients are in accordance with a valid prescription.

However, this regulation is still less effective in suppressing the over-the-counter sale of antibiotics in pharmacies and drug stores. Therefore, revision and improvement of the regulation are needed to be more in line with current conditions<sup>43</sup>. Regulations related to controlling antibiotic use need to be strengthened through policy revisions and increased law enforcement. Supervision of pharmacies and health facilities must be tightened by implementing a periodic inspection system and providing stricter sanctions for violators of antibiotic distribution rules<sup>44</sup>. With these stricter regulations, it is hoped

<sup>&</sup>lt;sup>43</sup> Djawaria, Setiadi, and Setiawan, "Pengembangan Kuesioner Dan Identifikasi Faktor Penyebab Penjualan Antibiotik Tanpa Resep Dokter Di Komunitas Kota Surabaya."

<sup>&</sup>lt;sup>44</sup> A. Zaffagnini et al., "Enforcing Surveillance of Antimicrobial Resistance and Antibiotic Use to Drive Stewardship: Experience in a Paediatric Setting,"

that antibiotic misuse can be minimized and their distribution can be more controlled. For example, the government can tighten sanctions for pharmacies or drug stores that are proven to sell antibiotics without a doctor's prescription. In addition to larger fines, revoking business licenses for repeat violators can be an effective step. The government must also ensure that all health facilities have a transparent recording system related to antibiotic use to facilitate monitoring and evaluation.

In addition, law enforcement is an important aspect in controlling antibiotic use. Currently, weak law enforcement is the main factor causing the rampant sale of antibiotics without a prescription. Effective law enforcement is key to controlling the use of antibiotics without a prescription<sup>45</sup>. Although there are regulations, law enforcement is often inconsistent. Based on field observations, only 5% of perpetrators received written warnings from the health office regarding the use of antibiotics without a doctor's prescription.

Therefore, efforts are needed to strengthen the monitoring mechanism and law enforcement against pharmacies that violate the rules. To overcome this, several steps can be applied, namely:

a. Revision of Regulations regarding the Sale of Drugs in Pharmacies and Drug Stores

Regulations on pharmacies and drug stores need to be updated to tighten the sale of antibiotics. Revised regulations also need to include stricter rules for drug suppliers and distributors. The distribution of antibiotics must be strictly monitored so that there are no loopholes for pharmacies or drug stores to obtain antibiotics without going through official procedures. With these stricter regulations, it is hoped that antibiotic misuse can be minimized and their distribution can be more controlled. For example, the government can tighten sanctions for pharmacies or drug stores that are proven to sell antibiotics without a doctor's prescription. In addition to larger fines, revoking business licenses for repeat violators can be an effective step.

Hospital Infection 144 (2024): 14-19. Iournal of https://doi.org/10.1016/j.jhin.2023.12.001.

<sup>&</sup>lt;sup>45</sup> Kurdi et al., "Assessment of Knowledge and Attitude toward the New Antibiotic Dispensing Law and Its Effect on Antibiotic Use in Saudi Arabia."

b. Increased Inspections and Raids at Pharmacies and Drug Stores

The government needs to increase the intensity of direct supervision of pharmacies and drug stores to ensure compliance with regulations. Periodic raids can be conducted to detect illegal sales of antibiotics and impose sanctions on violators.

c. Implementation of Stricter Sanctions

Pharmacies or drug stores that violate the rules must be given strict sanctions, such as larger fines or revocation of their business licenses. In addition, health workers who are proven to be involved in the illegal distribution of antibiotics must be subject to administrative and criminal sanctions in accordance with applicable provisions.

#### 2) Increasing Public Awareness

Many people still consider antibiotics as a multipurpose drug to treat various diseases, including flu and fever, without understanding the negative impacts of improper use. Low public awareness of the importance of proper antibiotic use has led to an increase in cases of antibiotic resistance, which has the potential to pose a major threat to public health<sup>46</sup>. To overcome this problem, various comprehensive and sustainable strategies are needed to increase public awareness of the dangers of using antibiotics without a doctor's prescription. Some strategies that can be implemented include:

a. Massive Public Education Campaign

Public education campaigns should be more massively carried out through various communication channels, such as mass media, social media, and education programs in schools and local communities. Campaign materials should explain in simple terms the dangers of antibiotic resistance and the importance of rational antibiotic use. In addition, the distribution of infographics, educational videos, and

<sup>46</sup> Nam Vinh Nguyen et al., "Outpatient Antibiotic Prescribing for Acute Respiratory Infections in Vietnamese Primary Care Settings by the WHO AWaRe (Access, Watch and Reserve) Classification: An Analysis Using Routinely Collected Electronic Prescription Data," *The Lancet Regional Health - Western Pacific* 30, no. October 2022 (2023): 100611, https://doi.org/10.1016/j.lanwpc.2022.100611.

testimonials from patients who have experienced antibiotic resistance can increase public understanding more effectivelv<sup>47</sup>.

- b. Counseling in Schools and the Workplace Health education about antibiotics should start early. Schools can include material about antibiotic resistance in the health education curriculum. In addition, companies can also hold health seminars to raise employee awareness about the dangers of using antibiotics without a prescription. This counseling will help shape a wiser mindset in the use of antibiotics in the family and community environment<sup>48</sup>.
- c. Community Participation in Supervision The community also needs to be involved in monitoring antibiotic abuse. The government can provide a complaint channel for the community who find pharmacies or drug stores selling antibiotics without a prescription. With active participation from the community, controlling antibiotic abuse can be more effective, as well as creating collective awareness of the importance of wise antibiotic use49.

# 3) Capacity Building of Health Workers

Health workers, including doctors, nurses, and pharmacists, have a crucial role in controlling antibiotic use. They are not only responsible for prescribing and providing medication, but also for educating patients about the proper use of antibiotics<sup>50</sup>.

47 Herawati et al., "Interview-Based Cross-Sectional Needs Assessment to Advance the Implementation of an Effective Antibiotic Stewardship Program in Indonesian Hospitals."

<sup>&</sup>lt;sup>48</sup> Faiz Ullah Khan et al., "Knowledge, Attitude, and Practice on Antibiotics and Its Resistance: A Two-Phase Mixed-Methods Online Study among Pakistani Community Pharmacists to Promote Rational Antibiotic Use," International Journal of Environmental Research and Public Health 18, no. 3 (2021): 1-16, https://doi.org/10.3390/ijerph18031320.

<sup>&</sup>lt;sup>49</sup> Areej M. Alajmi et al., "Antimicrobial Resistance Awareness, Antibiotics Prescription Errors and Dispensing Patterns by Community Pharmacists in Saudi Arabia," Journal of Infection and Public Health 16, no. 1 (2023): 34-41, https://doi.org/10.1016/j.jiph.2022.11.026.

<sup>&</sup>lt;sup>50</sup> O. J. Dyar et al., "How Can We Improve Antibiotic Prescribing in Primary Care?" Expert Review of Anti-Infective Therapy 14, no. 4 (2016): 403–413, https://doi.org/10.1586/14787210.2016.1151353.

However, several obstacles such as lack of training, limited resources, and pressure from patients who request excessive antibiotics often become obstacles in implementing this policy. With the increasing threat of antibiotic resistance, health workers must be equipped with adequate skills and knowledge to be able to provide quality health services<sup>51</sup>. Without a strong understanding of antibiotic resistance and the principles of wise antibiotic use, health workers can be a factor that exacerbates this problem, both directly and indirectly<sup>52</sup>.

To improve the capacity of health workers in handling antibiotic abuse, several strategies need to be implemented effectively and sustainably. Here are some steps that can be taken:

#### a) Ongoing Training and Workshops

One of the main efforts to improve the capacity of health workers is through regular training and workshops. These programs should be designed to provide a deeper understanding of antibiotic resistance, indications for correct antibiotic use, and effective communication techniques in dealing with patients who request excessive antibiotics<sup>53</sup>. For example, the Indonesian Ministry of Health can collaborate with medical universities and professional organizations such as the Indonesian Doctors Association (IDI) and the Indonesian Pharmacists Association (IAI) to conduct training based on the latest scientific evidence. This training can also include simulations of communication between health workers and patients to improve skills in explaining the importance of wise antibiotic use.

b) Development of Comprehensive Clinical Guidelines
To ensure that health workers have a clear reference in
prescribing antibiotics, it is necessary to develop and
disseminate comprehensive clinical guidelines. These
guidelines should contain information on the types of

<sup>&</sup>lt;sup>51</sup> Kurdi et al., "Assessment of Knowledge and Attitude toward the New Antibiotic Dispensing Law and Its Effect on Antibiotic Use in Saudi Arabia."

H. Faure et al., "Déterminants de La Prescription Ou de La Non-Prescription d'antibiotiques En Médecine Générale," Medecine et Maladies Infectieuses 39, no. 9 (2009): 714–21, https://doi.org/10.1016/j.medmal.2009.05.002.

Zaffagnini et al., "Enforcing Surveillance of Antimicrobial Resistance and Antibiotic Use to Drive Stewardship: Experience in a Paediatric Setting."

infections that require antibiotics, the right choice of antibiotics, and protocols for treating patients who do not require antibiotics. Currently, several large hospitals in Indonesia have implemented the Antimicrobial Stewardship Program (ASP) which helps doctors and pharmacists determine the most appropriate antibiotic therapy for patients. Such programs need to be expanded to various health facilities, including community health centers and clinics, so that all health workers have the same standards in treating patients.

c) Improving Supervision and Evaluation of Health Worker **Practices** 

To ensure that the rational antibiotic use policy is truly implemented, a strict monitoring and evaluation mechanism is needed for the practices of health workers. The government can develop a medical audit system that assesses the extent to which doctors and pharmacists comply with antibiotic use guidelines. Periodic inspections at pharmacies and clinics can also be carried out to ensure that there is no practice of selling antibiotics without a Based field observations. prescription. on pharmacies in Indonesia still sell antibiotics without a prescription due to the lack of strict supervision from the authorities. Therefore, strengthening regulations and monitoring systems must be carried out to ensure health workers' compliance with applicable policies.

# 4) Infrastructure Optimization and Monitoring System

Currently, the monitoring system for the distribution and use of antibiotics still faces various obstacles. One of the main problems is the lack of supporting infrastructure that allows for stricter monitoring of antibiotic sales and consumption. Most pharmacies and drug stores still sell antibiotics without a doctor's prescription, even though there are regulations prohibiting this practice. In addition, the absence of an integrated recording system makes it difficult to monitor antibiotic use patterns in the community<sup>54</sup>. To overcome this problem, strategic

<sup>&</sup>lt;sup>54</sup> Irfan A. Rather et al., "Self-Medication and Antibiotic Resistance: Crisis, Current Challenges, and Prevention," Saudi Journal of Biological Sciences 24, no. 4 (2017): 808–12, https://doi.org/10.1016/j.sjbs.2017.01.004.

steps are needed to improve infrastructure and strengthen a stricter and more efficient monitoring system<sup>55</sup>. Here are some strategies that can be implemented:

a. Development of Electronic Recording System (E-Prescription)

One crucial step in optimizing supervision is the implementation of an e-prescription system in all health facilities and pharmacies. With this system, every purchase of antibiotics must be recorded in a national database that allows real-time monitoring by the government and health authorities. E-prescriptions can also help ensure that only patients who really need antibiotics can access them, reducing the risk of misuse<sup>56</sup>. Countries such as Sweden and the UK have successfully implemented well-integrated e-prescription systems, allowing health workers and the government to monitor antibiotic use more closely. Indonesia can adopt a similar system by integrating data between hospitals, clinics, pharmacies, and local health offices.

b. Increased Supervision of Pharmacies and Health Facilities

The system of periodic inspections of pharmacies and health facilities should be strengthened to ensure compliance with antibiotic use regulations. The government can implement a risk-based audit system, where pharmacies with a history of violations are monitored more often and given strict sanctions if they continue to violate the rules<sup>57</sup>. Based on field observations, only about 5% of perpetrators who violate the rules receive a written warning from the health office. This figure shows that law enforcement is still very weak and needs to be improved. One solution is to increase the number of supervisors and apply stricter sanctions to pharmacies that sell antibiotics without a doctor's prescription.

Herawati et al., "Interview-Based Cross-Sectional Needs Assessment to Advance the Implementation of an Effective Antibiotic Stewardship Program in Indonesian Hospitals."

<sup>&</sup>lt;sup>56</sup> Ralalicia Limato et al., "Optimizing Antibiotic Use in Indonesia: A Systematic Review and Evidence Synthesis to Inform Opportunities for Intervention," *The Lancet Regional Health - Southeast Asia* 2, no. 6 (2022), https://doi.org/10.1016/j.lansea.2022.05.002.

Djawaria, Setiadi, and Setiawan, "Pengembangan Kuesioner Dan Identifikasi Faktor Penyebab Penjualan Antibiotik Tanpa Resep Dokter Di Komunitas Kota Surabaya."

#### Implementation of Digital Technology in Supervision

Digital technology can be an effective solution in improving the monitoring system for antibiotic use. The government can develop a mobile-based application that allows the public to report illegal antibiotic sales anonymously<sup>58</sup>. With a technologybased complaint system, it is hoped that the public can be more active in controlling antibiotic misuse. In addition, the use of artificial intelligence (AI) technology in analyzing antibiotic use data can also help detect suspicious patterns. AI can be used to identify pharmacies or areas that have an unreasonable level of antibiotic sales, so that preventive measures can be taken immediately.

#### 5) Increasing Cross-Sector Collaboration

Cross-sector collaboration is a strategic solution in dealing with antibiotic abuse. By involving various parties, control strategies can be more focused and integrated<sup>59</sup>. Each sector has a complementary role in building stronger policies, improving supervision, and educating the public about the correct use of antibiotics<sup>60</sup>. Strategies that can be carried out in efforts to improve cross-sector collaboration include:

a. Collaboration between Government and Health Workers The government, both at the central and regional levels, must work together with health workers to implement stricter regulations on the distribution and use of antibiotics. The Ministry of Health, the Food and Drug Monitoring Agency (BPOM), and regional health offices

58 Anaïs Essilini et al.. "French General Practitioners' and Patients' Acceptability of a Public Commitment Charter and Patient Information Leaflets Targeting Unnecessary Antibiotic Use: A Qualitative Study," Antimicrobial Resistance and Infection Control 11, no. 1 (2022): 1-9, https://doi.org/10.1186/s13756-022-01065-3.

<sup>&</sup>lt;sup>59</sup> M. A. Bouldouyre et al., "Mise En Place Des Centres Régionaux En Antibiothérapie (CRAtb): Définition et Rôle de Ces Nouveaux Acteurs Du Bon Usage En Antibiothérapie En France Establishment of Regional Antimicrobial Stewardship Coordination Centres (CRAtb) in French Administrative," Journal de Pediatrie et de Puericulture 37, no. 1 (2024): 8-14, https://doi.org/10.1016/j.jpp.2023.10.002.

<sup>60</sup> Nguyen et al., "Outpatient Antibiotic Prescribing for Acute Respiratory Infections in Vietnamese Primary Care Settings by the WHO AWaRe (Access, Watch and Reserve) Classification: An Analysis Using Routinely Collected Electronic Prescription Data."

need to ensure that all pharmacies and health facilities only distribute antibiotics based on a doctor's prescription. In addition, health workers must be given regular training to improve their understanding of treating patients who require antibiotics and to explain to patients why antibiotics should not be used carelessly. One example of the success of this collaboration can be seen in the Healthy Living Community Movement (GERMAS) program which involves medical personnel in educating the public about the rational use of antibiotics. This program has helped raise public awareness about the dangers of using antibiotics without medical supervision.

- b. Partnership with Academics and Research Institutions Academics and research institutions have an important role in providing data and scientific studies related to antibiotic resistance and the effectiveness of policies that implemented. Research conducted been universities and research institutions can help the government in designing evidence-based policies to address antibiotic misuse. For example, research conducted by several universities in Indonesia has shown that more than 60% of reported cases of bacterial infections in major hospitals in Jakarta showed resistance to first-generation antibiotics. This data can be used by the government to develop more effective control strategies.
- c. The Role of the Pharmaceutical Industry in Controlling the Distribution of Antibiotics

The pharmaceutical industry has a big responsibility to ensure that antibiotic distribution is only carried out to authorized parties, such as hospitals and official pharmacies<sup>61</sup>. Therefore, there needs to be a stricter monitoring mechanism in the antibiotic distribution chain, including a transparent reporting system to prevent misuse. One effort that can be made is to implement a unique code system for each antibiotic product sold, so that

Neusa F. Torres et al., "The Use of Non-Prescribed Antibiotics; Prevalence Estimates in Low-and-Middle-Income Countries. A Systematic Review and Meta-Analysis," Archives of Public Health 79, no. 1 (2021): 1–15, https://doi.org/10.1186/s13690-020-00517-9.

its distribution can be tracked more easily<sup>62</sup>. Several countries have implemented this system to ensure that antibiotics are not misused by irresponsible parties.

d. Collaboration with Professional Organizations Religious Institutions

Professional organizations such as the Indonesian Doctors Association (IDI), the Indonesian Pharmacists Association (IAI), and the Indonesian National Nurses Association (PPNI) can play a role in overseeing the practices of health workers and ensuring that they follow established antibiotic use guidelines. In addition, religious institutions can also contribute to raising public awareness through approaches based on moral and religious values. For example, the Indonesian Ulema Council (MUI) can issue a fatwa or appeal to Muslims about the importance of rational drug use and not misusing antibiotics. This can raise public awareness, especially in areas with high levels of religiosity.

By implementing a comprehensive and evidence-based strategy, it is hoped that antibiotic abuse can be reduced significantly, so that antibiotic resistance can be prevented and public health can be better maintained in the future. Support from all parties is needed to realize a stronger and more sustainable health system in facing the challenges of antibiotic resistance. Through good collaboration, Indonesia can ensure that the use of antibiotics is carried out wisely and only for medical purposes that are truly necessary.

#### E. Conclusion

Controlling the use of antibiotics without a doctor's prescription in Indonesia requires a comprehensive and sustainable approach. Although related regulations have been in place, their implementation still faces various challenges, such as weak supervision, low public awareness, and limitations in infrastructure and monitoring systems. Therefore, it is necessary to strengthen regulations and stricter law enforcement, increase public awareness through massive education, and strengthen the

<sup>62</sup> Hossain et al., "Antibiotic Prescription from Qualified Sources for Children with Fever/Cough: Cross-Sectional Study from 59 Low- and Middle-Income Countries."

capacity of health workers in prescribing and distributing antibiotics wisely. In addition, optimizing the monitoring system through digital technology and e-prescriptions can increase transparency and accuracy in monitoring antibiotic distribution. Cross-sector collaboration between the government, health workers, academics, and the community is also a key factor in suppressing antibiotic misuse and preventing an increase in antimicrobial resistance. With an integrated strategy and full support from all stakeholders, more effective control of antibiotic use in Indonesia can be realized to protect public health at large.

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