



# ПРОФИЛАКТИКА ИНФЕКЦИОННЫХ ЗАБОЛЕВАНИЙ

## PREVENTION OF INFECTIOUS DISEASES

© AJENG ILLASTRIA ROSALINA, 2026



Ajeng Illastia Rosalina

### Enhancing Indonesian FDA Supervision to Combat Antimicrobial Resistance: Regulatory Gaps and Multifaceted Solutions

Indonesian FDA Regional Office in Jakarta, Jakarta, 13870, Republic of Indonesia

#### ABSTRACT

**Introduction.** Antimicrobial resistance (AMR) is a mounting public health threat in Indonesia, fueled by widespread non-prescription antibiotic sales and limited regulatory effectiveness.

**The purpose of the study.** The purpose of this study was to assess prescription adherence, patterns of antibiotic supply, and regulatory violations by analyzing 2023 data from the Indonesian Food and Drug Authority's Jakarta Regional Office.

**Materials and methods.** This study analyzes 2023 inspection data from 105 Jakarta pharmacies, randomly and purposively sampled from 2,735 registered facilities, to assess prescription compliance, supply patterns, and regulatory breaches. Using a cross-sectional approach, we examined antibiotic dispensing against prescription records, documented stock levels, identified frequently supplied antibiotics, and explored the reasoning for non-prescription sales.

**Results.** Results revealed that 37% of antibiotics were provided without prescriptions, highlighting pervasive self-medication. Amoxicillin dominated supplies (63%), followed by Cefixime and Metronidazole, heightening resistance risks. Regulatory tools, mainly administrative reprimands, proved inadequate; notably, 20% of non-prescription antibiotics were distributed to unregulated midwives, underscoring oversight weaknesses. Fragmented education among health providers and the public further limits efforts to curb AMR.

**Research limitation.** The study is limited by its reliance on inspection data from a single year and region, which may not capture trends elsewhere in Indonesia or ongoing changes in pharmacy practice.

**Conclusions.** To address these systemic issues, we recommend stronger penalties, enhanced oversight — especially regarding midwife practices — real-time sales monitoring, integrated public education campaigns aligned with WHO guidance, and coordinated efforts across agencies to control online antibiotic sales.

**Keywords:** antimicrobial resistance; Indonesian FDA; non-prescription antibiotic sales; pharmaceutical regulatory enforcement

**Compliance with ethical standards.** The study does not require submission of the opinion of the biomedical ethics committee or other documents.

**For citation:** Ajeng Illastia Rosalina. Enhancing Indonesian FDA Supervision to Combat Antimicrobial Resistance: Regulatory Gaps and Multifaceted Solutions. *Zdravookhranenie Rossiiskoi Federatsii / Health Care of the Russian Federation, Russian journal.* 2026; 70(1): 43–49. <https://doi.org/10.47470/0044-197X-2026-70-1-43-49> <https://elibrary.ru/yjccue> (in Russian)

**For correspondence:** Ajeng Illastia Rosalina, e-mail: [ajengrosalyne.air@gmail.com](mailto:ajengrosalyne.air@gmail.com)

**Funding.** The study had no sponsorship.

**Conflict of interest.** The authors declare no conflict of interest.

Received: June 23, 2025 / Revised: November 25, 2025 / Accepted: December 17, 2025 / Published: March 4, 2026

Адженг Илластрия Розалина

### Усиление надзора со стороны Управления по контролю за продуктами питания и лекарствами Индонезии в борьбе с антибиотикорезистентностью: пробелы в регулировании и комплексные решения

Региональное отделение Управления по контролю за продуктами питания и лекарствами, 13870, Джакарта, Республика Индонезия

#### РЕЗЮМЕ

**Введение.** В Индонезии растущую угрозу для общественного здравоохранения представляет собой антибиотикорезистентность, усугубляемая широко распространённой безрецептурной продажей антибиотиков (АБ) и ограниченной эффективностью регулирования.

**Цель исследования** — оценить соблюдение режима приёма лекарств по рецепту, структуру поставок АБ и нарушения нормативных требований путём анализа данных за 2023 г. из регионального отделения Управления по контролю за продуктами питания и лекарствами Индонезии в Джакарте.

**Материалы и методы.** Проанализированы данные проверок, проведённых в 2023 г. в 105 аптеках Джакарты, отобранных случайным и целенаправленным образом из 2735 зарегистрированных учреждений, для оценки соблюдения рецептурных требований, моделей

поставок и нарушений нормативных требований. Используя метод поперечных срезов, проанализировали отпуск АБ по рецепту, задокументировали объём запасов, установили часто отпускаемые АБ и исследовали поводы для безрецептурной продажи.

**Результаты.** Оказалось, что 37% АБ были отпущены без рецепта, что подчёркивает широкую распространённость самолечения. В основном, отпускали амоксициллин (63%), за которым следовали цефиксим и метронидазол, что повышает риск развития резистентности. Административные меры, в основном административные, оказались неэффективными; в частности, 20% безрецептурных АБ были закуплены нелегальными акушерками, что указывает на несовершенство мер надзора. Фрагментированное обучение медицинских работников и населения ещё больше ограничивает усилия по борьбе с устойчивостью к АБ.

**Ограничение исследования.** Исследование ограничено учётом данных инспекций за один год, из одного региона, что может не отражать тенденции в других регионах Индонезии или текущие изменения в фармацевтической практике.

**Выводы.** Для решения этих системных проблем мы рекомендуем ужесточить наказания, усилить надзор, особенно в отношении акушерской практики, осуществлять мониторинг продаж в режиме реального времени, проводить комплексные кампании по информированию общественности в соответствии с рекомендациями ВОЗ и координировать усилия различных ведомств по контролю за онлайн-продажей АБ.

**Ключевые слова:** *антибиотикорезистентность; Индонезийское управление по контролю за продуктами питания и лекарствами; свободная продажа антибиотиков; контроль за соблюдением нормативных требований в фармацевтической отрасли*

**Соблюдение этических стандартов.** Для проведения исследования не требуется предоставление заключения комитета по биомедицинской этике или других документов.

**Для цитирования:** Адженг Илластрия Розалина. Усиление надзора со стороны Управления по контролю за продуктами питания и лекарствами Индонезии в борьбе с антибиотикорезистентностью: пробелы в регулировании и комплексные решения. *Здравоохранение Российской Федерации*. 2026; 70(1): 43–49. <https://doi.org/10.47470/0044-197X-2026-70-1-43-49> <https://elibrary.ru/yjccue>

**Для корреспонденции:** *Адженг Илластрия Розалина*, e-mail: [ajengrosalyne.air@gmail.com](mailto:ajengrosalyne.air@gmail.com)

**Финансирование.** Исследование не финансировалось.

**Конфликт интересов.** Автор заявляет об отсутствии конфликта интересов.

Поступила: 23.06.2025 / Поступила после доработки: 25.11.2025 / Принята к печати: 17.12.2025 / Опубликовано: 04.03.2026

## Introduction

Antimicrobial resistance (AMR) is a natural occurrence in which bacteria adapt to resist the effects of antibiotics, rendering them seemingly ineffectual [1]. The advent of antibiotics in clinical practice was undoubtedly the most significant medical advancement of the 20<sup>th</sup> century [2]. Antibiotics not only treat infectious infections but also enable numerous contemporary medical operations, such as cancer therapy, organ transplantation, and open-heart surgery [3].

The absence of effective antibiotics will significantly impede various medical disciplines, including surgery, neonatal care, oncology, critical care, and transplantation, all of which rely on effective antibiotic treatment. Our capacity to address national security threats, such as bioterrorism and pandemics, is significantly compromised. The depletion of effective antibiotics will lead to a significant rise in morbidity and mortality due to infections. AMR is a significant global issue, prompting the World Health Organization (WHO) to choose it as the primary theme for World Health Day 2011 [4].

Antibiotic overuse and misuse, which are the result of irrational prescribing and dispensing, self-medication, and irrational prescribing, may result in serious adverse events, recurrent infections, AMR, increased treatment costs, and poor health outcomes [5]. The sale of antibiotics without prescriptions is dangerous as it contributes to the promotion of AMR; consequently, it is predominantly prohibited on a global scale [6]. However, the practice of self-medication with antimicrobial agents is extensively documented among patients worldwide [7]. Self-medication with antibiotics, which are typically obtained from retail outlets [8] which encompassed retail pharmacies, groceries, medicine stores, and medicine peddlers, from which it was effortless and convenient [9]. In addition to physical outlets, antibiotics can be easily obtained online without the need for a prescription. Even worse, the inherent framework of these transactions promotes self-medication and diminishes the quality of care, which further exacerbates the issue of antibiotics from the online market [10].

Several factors contributing to the phenomenon of self-medication encompass inadequate regulation of

prescription practices, insufficient understanding of pharmacological effects, elevated expenses associated with accessing healthcare services, recommendations from peers, prior personal experiences, extended waiting periods, and considerable distances to healthcare facilities [11]. The primary motivation for purchasing antibiotics directly from retail outlets rather than through a clinical consultation was to minimize the direct costs of treatment (such as the cost of medical consultation and travel to the clinic) and the indirect costs of lost income. This was especially crucial for individuals with low-paying or insecure jobs [12].

AMR is a catastrophic global health threat that has the potential to undermine fundamental healthcare interventions and jeopardize decades of medical progress. Indonesia acknowledges the urgency of this issue and has explicitly incorporated AMR management into its national policy framework for 2020–2024. The strategic emphasis is on disease control through AMR mitigation [13]. The Indonesian Food and Drug Authority is a critical player in this endeavor, as it is the national regulatory authority responsible for the implementation of targeted programs to combat AMR. These initiatives encompass supervisory activities that enforce prescription-only dispensing at healthcare facilities and educational initiatives that are intended to discourage the public from self-medication with antibiotics.

Nevertheless, a critical implementation deficit continues to exist. Despite the operational activities of Indonesian Food and Drug Authority and its alignment with core WHO recommendations for enhancing AMR awareness through education and communication [14], these essential programs lack formal integration and dedicated resourcing within the overarching national AMR Action Plan. This disconnects leads to a fragmented and disjointed approach, in which BPOM's regulatory and pedagogical endeavours operate in isolation rather than as a coordinated 14 component of the national strategy. As a result, the potential impact of these initiatives is substantially diminished, thereby impeding comprehensive progress against AMR drivers, such as the pervasive non-prescription antibiotic sales identified in Jakarta.

Therefore, the objective of this research is to identify improved, multifaceted regulatory, educational, and

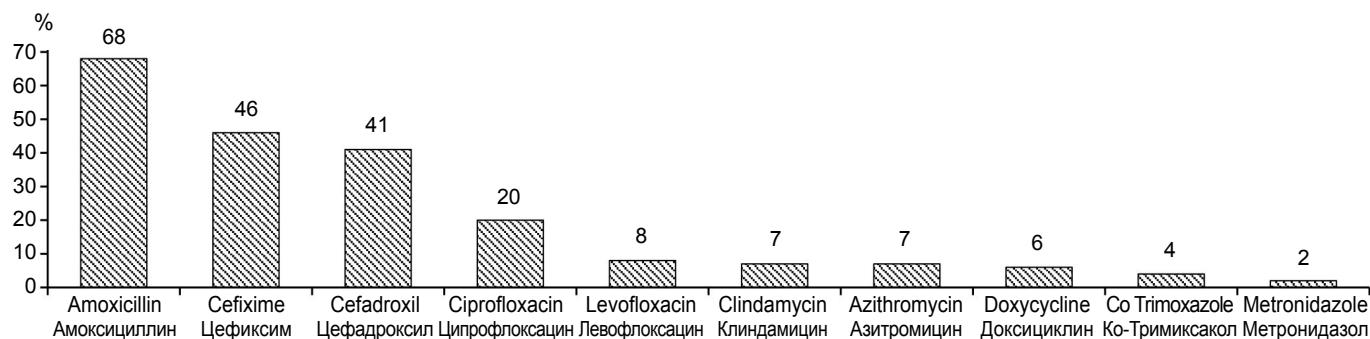


Fig. 1. Prevalence use of antibiotic in Jakarta, Indonesia, %.

Рис. 1. Распространённость применения АБ в Джакарте, Индонезия.

operational strategies for BPOM to enhance Indonesia's AMR containment. It specifically assesses intricate strategies to address identified gaps in enforcement, surveillance, practitioner supervision, and, most importantly, the strategic integration of societal education within the national framework.

**The purpose of the study** was to assess prescription adherence, patterns of antibiotic supply, and regulatory violations by analyzing 2023 data from the Indonesian Food and Drug Authority's Jakarta Regional Office.

### Methods

**Data management.** Data obtained from inspection activities conducted by Indonesian FDA Regional Office in Jakarta concerning pharmaceutical facilities during the year 2023. The evaluation is whether all antibiotic dispensing is based upon a medical prescription or whether it is dispensing without a medical prescription. The evaluation is conducted by comparing the amounts of antibiotics that have been dispensed with the prescription archive held in storage.

Additionally, supporting data included assessments of stock record for antibiotic products, the categories of antibiotics most commonly dispensed, personnel who dispensed antibiotics to patients without a medical prescription, the provision of information, education, and communication regarding the dispensing of antibiotics without a medical prescription, and the rationale for dispensing antibiotics without a physician's prescription beyond patient use.

**Population and sample size.** During the year 2023, the Indonesian FDA Regional Office in Jakarta conducted inspections of 105 pharmacy facilities. The numbers were collected from a population of 2,735 pharmacies distributed across the DKI Jakarta Province. The selection of the analyzed pharmacy facilities was based on both random and targeted criteria. Targeted sampling based on multiple criteria, including records from prior inspections, pharmacies that acquire substantial quantities of drugs from distributors, and newly established pharmacies that have not been previously inspected.

### Results

**Total prevalence of antibiotic supply.** The findings from this study clearly illustrate a significant reliance on Amoxicillin, Cefixime, and Metronidazole among antibiotic supplies dispensed in the studied pharmacies (Fig. 1). The prominence of Amoxicillin, constituting the highest percentage, highlights its prevalent use as a broad-spectrum antibiotic preferred for common infections due to its availability, affordability, and perceived effectiveness. This aligns with global trends, as

Amoxicillin remains one of the most frequently prescribed antibiotics worldwide, often resulting in increased resistance patterns [8]. The evidence aligns with that obtained by A.K. Owusu-Ofori et al., indicating that Amoxicillin predominates as the principal agent, underscoring its extensive availability and perceived efficacy in addressing common infections. Metronidazole is probably utilized for gastrointestinal and dental diseases. Ciprofloxacin and Erythromycin constitute minor yet significant quantities, potentially associated with their use in urinary tract and respiratory infections, respectively [15].

**The sale of antibiotics without a prescription.** Self-medication may assist in managing acute illnesses that may not require medical treatment, or recurring conditions previously diagnosed during prior visits. When executed appropriately, it may expedite patient alleviation by ensuring timely access to medication. It can be an economical alternative in environments with constrained resources, especially in low- and middle-income countries. Nonetheless, improper self-medication exposes the patient to numerous risks and disadvantages, including bad drug reactions, the emergence of AMR, the concealment of a more serious underlying ailment, and the failure to seek timely medical consultation [16].

**Figure 2** illustrates the prevalence of antibiotic self-medication in Jakarta. The chart outlines the distribution of antibiotic sales, categorizing them according to whether they were acquired with or without a medical prescription. The data indicates that 63% of antibiotic sales were conducted with a medical prescription, whereas 37% were dispensed without a prescription, thereby highlighting a considerable prevalence of self-medication. The notable incidence of antibiotic distribution without prescriptions revealed in the

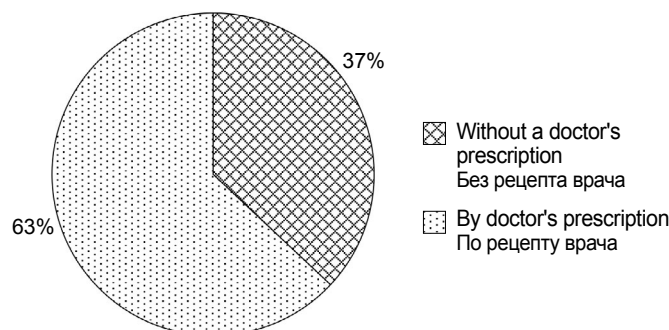


Fig. 2. Comparative of antibiotic sales.

Рис. 2. Сравнительный анализ продаж антибиотиков: без рецепта врача и по рецепту врача.

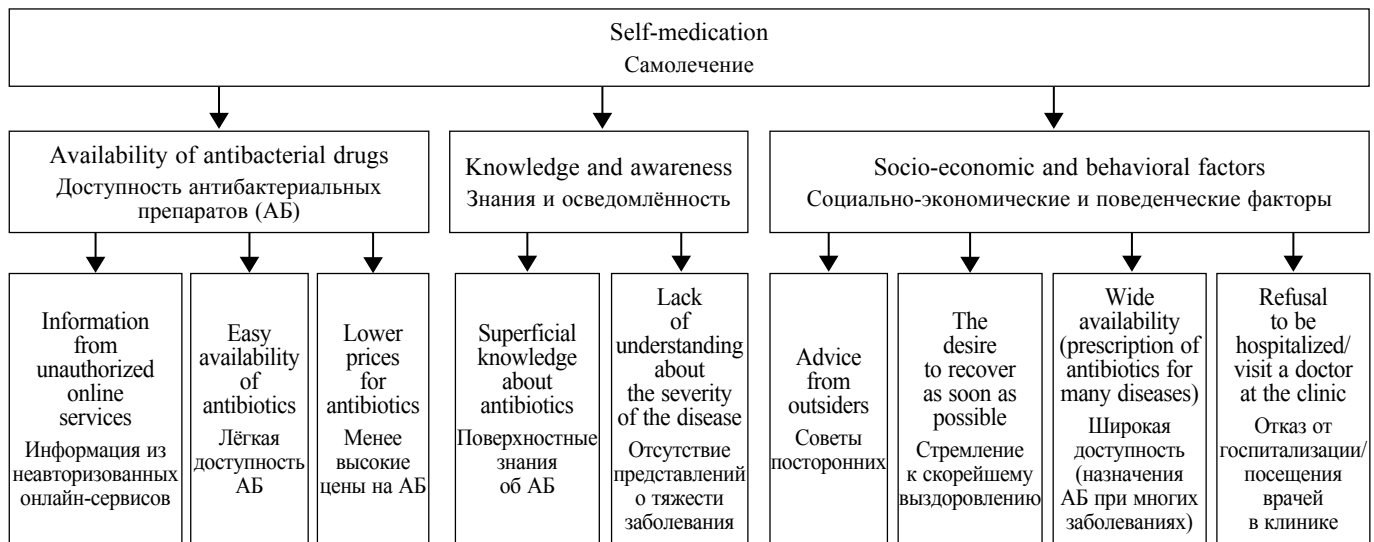


Fig. 3. Reason for self-medication.

Рис. 3. Причина для самолечения.

study (37%) highlights a crucial obstacle to regulatory efficacy in Indonesia. Notwithstanding the regulatory frameworks created by the Indonesian FDA to mitigate unlawful antibiotic sales, these findings indicate deficiencies in implementation or enforcement, facilitating ongoing self-medication and improper antibiotic usage.

Among the total antibiotics provided without a medical prescription, 20% of pharmacies acknowledged distributing them to independent midwives and independent practitioners, in addition to directly supplying patients. In fact, Indonesian FDA absences the jurisdiction to conduct oversight on independent midwifery practices. In 2018, an escalation of vaccine oversight, which also encompassed independent midwife practices involved in vaccine administration, revealed that 12 of the 20 midwife practices assessed were improperly storing and dispensing antibiotics to patients. This is contrary to the provisions of laws and regulations.

## Discussion

The total supply of antibiotics showed a heavy reliance on Amoxicillin. This pattern reveals potential hazards, such as increased AMR, and underscores the necessity for public education on prudent antibiotic use [15]. The development of resistance correlates with the frequency of antibiotic utilization. Resistance to a particular antibiotic might result in resistance across an entire class of related antibiotics, as several belong to the same category of medications. Resistance that arises in a single organism or place can disseminate swiftly and unpredictably, for example, via the exchange of genetic material across diverse bacteria, thereby impacting antibiotic efficacy against a broad spectrum of illnesses and disorders [14]. The 2019 Antibiotic Resistance Threats Report by the Centers for Disease Control and Prevention (CDC) indicates that over 2.8 million antibiotic-resistant infections occur annually in the United States, leading to more than 35,000 fatalities [17].

The widespread prescription of Cefixime and Metronidazole signifies prevalent prescribing patterns that may suggest inappropriate antibiotic utilization, especially for gastrointestinal and respiratory infections, which could be addressed with alternative clinical strategies or more targeted antibiotics [18, 19]. Furthermore, these findings indicate

an urgent need for enhancing pharmacists' accountability, perhaps through structured training and certification processes designed to ensure adherence to appropriate dispensing practices. Policymakers must leverage these insights to refine current regulations, expand monitoring capabilities, and enhance public health education campaigns, thus fostering a responsible antibiotic stewardship culture and significantly reducing the risk of further AMR development in Indonesia.

The WHO's recent Global Antimicrobial Surveillance System (GLASS) indicates pervasive AMR among 500,000 individuals with documented bacterial illnesses across 22 nations. *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Klebsiella pneumoniae* were the most often reported resistant bacteria. Resistance to ciprofloxacin, a commonly utilized antibiotic for urinary tract infections, varied from 8.4% to 92.9% for *E. coli* and from 4.1% to 79.4% for *K. pneumoniae*, while penicillin resistance reached up to 51% in countries reporting to GLASS. In 2019, GLASS obtained data on MRSA bloodstream infections from 25 nations, regions, and zones, and *E. coli* bloodstream infections from 49 countries. The median incidence of methicillin-resistant *S. aureus* was 12.11% (IQR 6.4–26.4), while the median rate of *E. coli* resistant to third-generation cephalosporins was 36% (IQR 15.2–63.0) [20].

Antibiotic sale without medical prescription also reported by G. Nepal et al. (2018). In the Southeast Asian region, antibiotics are commonly utilized without a physician's prescription. Self-medication with antibiotics is associated with the potential for inappropriate drug utilization, which endangers patients through unpleasant drug reactions, obscuring symptoms of underlying conditions, and fostering microbial drug resistance [21].

Research indicates that individuals opted for self-medication with antibiotics for many reasons (Fig. 3):

- additional expenses incurred due to facility custody;
- presumed information regarding antibiotic usage;
- prolonged waiting periods necessitating referral to healthcare facilities;
- prior experience with analogous symptoms or antibiotics;
- the disease perceived as minor by the patient;
- advice from acquaintances or family; insufficient time for referral;

- financial constraints; discourteous conduct of healthcare personnel;
- lack of confidence in the effectiveness of antibiotics;
- uncertainty regarding the efficacy of antibiotics;
- experience with similar symptoms, coupled with a layperson's inability to recognise whether the administered medication is an antibiotic, leading to confusion and negligence in completing antibiotic therapy [22].

In addition to the factors mentioned above, F. Alhomoud et al. discovered in their study that the majority of pharmacists would administer antibiotics to patients without a prescription because they believed they had the requisite knowledge and experience. They also stated that they would only feel comfortable managing specific types of infections, such as throat infections, wound infections, or urinary tract infections. In contrast, complex infections require a physician's consultation [5].

Presently, the distribution of controlled substances (list G) without a physician's prescription at pharmaceutical service establishments is classified as a significant infraction. where the highest penalty imposed is an administrative sanction in the form of a formal reprimand [23]. Overseeing the distribution of pharmaceuticals is a significant difficulty in managing the drug supply chain, which comprises an integrated system involving the movement of items from suppliers, producers, and retailers to the final consumer. It entails a linkage among supervisory sectors, encompassing pharmaceutical industries, major pharmaceutical distributors, healthcare institutions, and retailers before to the delivery of pharmaceuticals to consumers or patients.

### Indonesian FDA program

One of the objectives of the Indonesian government's policy for 2020–2024 is to enhance disease control, with a specific strategy focused on managing AMR [13]. The government's current solution to this issue is to increase public education and awareness of the risks associated with purchasing controlled medications without a prescription. This is a component of the government's initiative to establish health check-ups with physicians as a critical step prior to the acquisition of medications [24].

**Educate.** Currently, educational initiatives within Indonesia's AMR strategy are operating in isolation. Indonesia's implementation of the World Health Organization's (WHO) explicit identification of the enhancement of public and professional awareness through communication, education, and training as a core pillar for combating AMR [14], remains fragmented. The Ministry of Health conducts specialized programs to educate physicians on the rational prescription of antibiotics, with a particular emphasis on minor infections [13]. At the same time, the Indonesian FDA (BPOM) implements campaigns to inform the public about the dangers of self-medication with antibiotics and initiatives to educate pharmacies on the prevention of non-prescription antibiotic sales. Although these educational initiatives are crucial, they are not strategically integrated or adequately funded within the national 2020–2024 AMR Action Plan. This gap between foundational WHO guidance, operational activities, and overarching national policy is substantial, and it has the potential to undermine the coherence and impact of educational interventions that are designed to alter the prescribing and consumption behaviors that are essential for AMR containment.

Preventive measures encompass the provision of health education to highlight the problems associated with antibiotic self-medication. These concerns are to utilizing a physician's

prior prescription to get antibiotics, administering antibiotics for minor ailments such as a sore throat, altering medications during self-medication, and discontinuing antibiotics upon symptom resolution. To educate and raise awareness, targeted advertisements will enlighten the public about various ailments and the importance of getting medical care from hospitals [25]. Education should also promote infection prevention techniques, and improve accessibility to information to avert the establishment of antimicrobial-resistant microorganisms [26].

**Supervision and Sanctions.** The WHO recommends that all retail outlets be registered and that antimicrobials be dispensed solely with a prescription [27]. Numerous studies in the country have demonstrated a substantial prevalence of over-the-counter antibiotic sales, resulting in self-medication practices [28].

The Indonesian FDA is responsible for the implementation of policies regarding the supervision of therapeutic products, narcotics, psychotropics, other addictive substances, traditional remedies, complementary products, and food safety. As a result, the supervision of pharmacies as providers of therapeutic products is a critical responsibility of FDA in each region [24].

B. Godman et al. (2021) assert that enhancing regulatory measures and oversight procedures is essential for combating AMR. Stringent regulatory enforcement measures, such as rigorous prescription audits and systematic monitoring of pharmaceutical dispensing processes, have been highly effective in diminishing inappropriate antibiotic usage across diverse international settings. The execution of targeted measures, including prescribing audits, obligatory prescription restrictions, and pharmacist responsibility, has shown considerable efficacy in regulating illogical antibiotic distribution behaviors worldwide. B. Godman et al. emphasize successful case studies in which augmented pharmacist education, uniform public health communication, and strengthened regulatory enforcement resulted in significant reductions in antibiotic abuse. Therefore, implementing such comprehensive strategies in Indonesia can significantly reduce AMR dangers. Strategic initiatives encompassing policy reforms, routine inspections, stringent penalties for non-compliance, and heightened awareness via targeted educational campaigns are highly advocated as effective measures to maintain antibiotic efficacy and protect public health in Indonesia [29].

Pharmacies also play a substantial role. Pharmacies are required to maintain the necessary licenses and comply with established pharmaceutical regulations, in addition to participating in government-sponsored educational and awareness campaigns. The government must implement stringent sanctions in the event of noncompliance and enhance oversight of pharmacies that dispense controlled medications without prescriptions [24]. N. Torres et al. conducted a study that concluded that the sale of antibiotics without a prescription could be resolved by enforcing compliance and accountability measures through law enforcement and accountability mechanisms. This would progressively eliminate the practices of self-medication with antibiotic and non-prescribed antibiotic dispensing by educating proprietors, pharmacists, and clients about the optimal way to use these medications [30].

### Consideration of policy frameworks in various nations

The prevention of AMR requires a multidisciplinary approach involving coordinated efforts and strategic planning among diverse stakeholders. In the United States, a key strategy to address AMR has been the reinforcement

of interagency collaboration across relevant federal entities to ensure cohesive policy implementation and resource allocation. Federal agencies involved in AMR, stewardship, and product research and development involve the HHS's CDC, FDA, NIH, BARDA, Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, Health Resources Services Administration, as well as the US Departments of Agriculture, Defense, Veterans Affairs, Homeland Security, State (including the US Agency for International Development), and Education [4].

Numerous initiatives have been implemented to enhance antimicrobial utilization and regulate its restricted application in nations like Azerbaijan. Following the price adjustments, distributors and corporations face substantial penalties if a pharmacy distributes medications to customers at unregulated prices. As a result, total antibiotic usage in Azerbaijan has been consistently decreasing in recent years [31]. In the past decade, prescription limitations and audits have proven to be the most effective intervention in Slovenia, leading to a reduced utilization of restricted antibiotics compared to unrestricted antibiotics [32]. In recent years, the Republic of Srpska has exhibited a reduced antibiotic consumption rate, potentially attributable to the Republic's healthcare and health insurance regulations that guarantee all patients access to quality healthcare services, including pharmaceuticals and alternative therapies [33]. In contrast to Poland, where authorities and various groups have initiated relatively minimal operations, the country had one of the highest rates of antimicrobial usage in Europe from 2007 to 2018 [34].

**Research limitation.** The study is limited by its reliance on inspection data from a single year and region, which may not capture trends elsewhere in Indonesia or ongoing changes in pharmacy practice.

## Conclusion

The pervasive misuse of antibiotics in Indonesia has exacerbated AMR, which poses a significant threat to public health. Significant issues that contribute to this challenge are revealed by key findings. According to the 2023 BPOM data, 37% of antibiotics in Jakarta are dispensed without prescriptions, indicating a high prevalence of self-medication. This practice promotes the development of AMR and irrational use. Enforcement gaps persist in spite of BPOM's regulatory supervision of pharmacies, as sanctions such as formal reprimands are insufficient deterrents. Furthermore, midwives operate independently of regulatory oversight, which complicates their endeavours. Resistance risks are further exacerbated by the market's dominant position of

antibiotics such as Amoxicillin (63% of supplies), Cefixime, and Metronidazole. Self-medication practices are perpetuated by structural drivers, such as economic barriers to healthcare access, poor public awareness, and complicity among chemists. These findings emphasise challenges to Indonesia's 2020–2024 AMR control strategy and mirror global concerns highlighted by WHO and CDC regarding AMR.

## Recommendations

Indonesia should implement a multifaceted strategy to enhance AMR containment. Initially, it is imperative to improve regulatory enforcement. As recommended by B. Godman et al. (2021) and N. Torres et al. (2020), this entails substituting reprimands with more severe penalties, including fines, license suspensions, or criminal liability, for pharmacies that dispense antibiotics without prescriptions. It is imperative to empower BPOM to supervise midwives and independent practitioners who are engaged in antibiotic dispensing, as well as to implement regular prescription audits and real-time sales monitoring, which are modelled after systems in Slovenia and Azerbaijan.

The second issue is the necessity of strengthening the healthcare system. Pharmacists must be held accountable for their antibiotic stewardship by mandating certification and associating licensure with regulatory compliance. Subsidised consultations for low-income groups will enhance public healthcare access and reduce the incidence of self-medication that is motivated by financial constraints.

Thirdly, it is essential to prioritise public education and awareness. Leveraging WHO communication frameworks, initiatives should involve media campaigns on social media and television platforms to inform the public about the legal requirements for purchasing antibiotics and the risks associated with AMR. Community engagement will be further enhanced by collaborating with schools, NGOs, and religious leaders to disseminate guidelines in local languages.

Finally, it is imperative to implement robust research and policy initiatives. It is imperative to expand BPOM's Jakarta pilot project to include nationwide monitoring of antibiotic supply chains and resistance patterns in order to ensure effective national surveillance. The BPOM, the Ministry of Health, and academia will be integrated to establish an interagency task force that is comparable to the CDC in the United States. This task force will enable the development of rapid response capabilities and collaborative AMR research. The comprehensive approach required to effectively combat AMR in Indonesia is completed by strengthening digital regulations through partnerships with e-commerce platforms to restrict the sale of non-prescription antibiotics online.

## REFERENCES / ЛИТЕРАТУРА

1. Annunziato G. Strategies to overcome Antimicrobial Resistance (AMR) making use of non-essential target inhibitors: a review. *Int. J. Mol. Sci.* 2019; 20(23): 5844. <https://doi.org/10.3390/ijms20235844>
2. Katz L., Baltz R.H. Natural product discovery: past, present, and future. *J. Ind. Microbiol. Biotechnol.* 2016; 43(2–3): 155–76. <https://doi.org/10.1007/s10295-015-1723-5>
3. Hutchings M.I., Truman A.W., Wilkinson B. Antibiotics: past, present and future. *Curr. Opin. Microbiol.* 2019; 51: 72–80. <https://doi.org/10.1016/j.mib.2019.10.008>
4. Spellberg B., Blaser M., Guidos R.J., Boucher H.W., Bradley J.S., Eisenstein B.I., et al. Combating antimicrobial resistance: policy recommendations to save lives. *Clin. Infect. Dis.* 2011; 52(Suppl. 5): S397–428. <https://doi.org/10.1093/cid/cir153>
5. Alhomoud F., Almahasnah R., Alhomoud F.K. “You could lose when you misuse” – factors affecting over-the-counter sale of antibiotics in community pharmacies in Saudi Arabia: a qualitative study. *BMC Health Serv. Res.* 2018; 18(1): 915. <https://doi.org/10.1186/s12913-018-3753-y>
6. Ngyedu E.K., Acolatse J., Akafity G., Incoom R., Rauf A., Seaton R.A., et al. Selling antibiotics without prescriptions among community pharmacies and drug outlets: a simulated client study from Ghana. *Expert Rev. Anti Infect. Ther.* 2023; 21(12): 1373–82. <https://doi.org/10.1080/14787210.2023.2283037>
7. Cabral C., Zhang T., Oliver I., Little P., Yardley L., Lambert H. Influences on use of antibiotics without prescription by the public in low- and middle-income countries: a systematic review and synthesis of qualitative evidence. *JAC Antimicrob. Resist.* 2024; 6(5): dlal65. <https://doi.org/10.1093/jacamr/dlael65>
8. Auta A., Hadi M.A., Oga E., Adewuyi E.O., Abdu-Aguye S.N., Adeloye D., et al. Global access to antibiotics without prescription

Профилактика инфекционных заболеваний

- in community pharmacies: A systematic review and meta-analysis. *J. Infect.* 2019; 78(1): 8–18. <https://doi.org/10.1016/j.jinf.2018.07.001>
9. Aponte-González J., González-Acuña A., Lopez J., Brown P., Eslava-Schmalbach J. Perceptions in the community about the use of antibiotics without a prescription: Exploring ideas behind this practice. *Pharm. Pract. (Granada)*. 2019; 17(1): 1394. <https://doi.org/10.18549/PharmPract.2019.1.1394>
  10. Mainous A.G. 3<sup>rd</sup>, Everett C.J., Post R.E., Diaz V.A., Hueston W.J. Availability of antibiotics for purchase without a prescription on the internet. *Ann. Fam. Med.* 2009; 7(5): 431–5. <https://doi.org/10.1370/afm.999>
  11. Chioro A., Coll-Seck A.M., Høie B., Moelock N., Motsoaledi A., Rajatanavin R., et al. Antimicrobial resistance: a priority for global health action. *Bull. World Health Organ.* 2015; 93(7): 439. <https://doi.org/10.2471/BLT.15.158998>
  12. Kotwani A., Joshi J., Lamkang A.S., Sharma A., Kaloni D. Knowledge and behavior of consumers towards the non-prescription purchase of antibiotics: An insight from a qualitative study from New Delhi, India. *Pharm. Pract. (Granada)*. 2021; 19(1): 2206. <https://doi.org/10.18549/PharmPract.2021.1.2206>
  13. Peraturan menteri koordinator bidang pembangunan manusia dan kebudayaan Republik Indonesia nomor 7 tahun; 2021. (in Indonesian)
  14. WHO. Global action plan on antimicrobial resistance; 2016.
  15. Owusu-Ofori A.K., Darko E., Danquah C.A., Agyarko-Poku T., Buabeng K.O. Self-medication and antimicrobial resistance: a survey of students studying healthcare programmes at a tertiary institution in Ghana. *Front Public Health.* 2021; 9: 706290. <https://doi.org/10.3389/fpubh.2021.706290>
  16. Amin E.T., Charles N., Fondugallah J.A., Fuaefac A., Mvilongo P.T.N., Ako-Arrey D., et al. Prevalence of antimicrobial self-medication among patients attending two hospitals in the Buea Health District, Cameroon. *Arch. Community Med. Public Health.* 2019; 5(1): 024–8. <https://doi.org/10.17352/2455-5479.000048>
  17. European Centre for Disease Prevention and Control (ECDC). Antimicrobial resistance in the EU/EEA (EARS-Net) – annual epidemiological report 2019. Stockholm; 2020.
  18. Mouanga-Ndzime Y., Bisseye C., Longo-Pendy N.M., Bignoumba M., Dikoumba A.C., Onanga R. Trends in *Escherichia coli* and *Klebsiella pneumoniae* urinary tract infections and antibiotic resistance over a 5-year period in Southeastern Gabon. *Antibiotics (Basel)*. 2024; 14(1): 14. <https://doi.org/10.3390/antibiotics14010014>
  19. Montes O., Escobar J., Reyes N. Complete genome and plasmid sequences of *Staphylococcus aureus* strain COL52-A5 isolated from a persistent nasal carrier. *Journal of Global Antimicrobial Resistance*, 2022; (28): 143–5. <https://doi.org/10.1016/j.jgar.2022.01.003>
  20. Montes O., Escobar J., Reyes N. Complete genome and plasmid sequences of *Staphylococcus aureus* strain COL52-A5 isolated from a persistent nasal carrier. *J. Glob. Antimicrob. Resist.* 2022; 28: 143–5. <https://doi.org/10.1093/jac/dkq412>
  21. Nepal G., Bhatta S. Self-medication with antibiotics in WHO Southeast Asian region: a systematic review. *Cureus*. 2018; 10(4): e2428. <https://doi.org/10.7759/cureus.2428>
  22. Yeika E.V., Ingelbeen B., Kemah B.L., Wirsy F.S., Fomengia J.N., van der Sande M.A.B. Comparative assessment of the prevalence, practices and factors associated with self-medication with antibiotics in Africa. *Trop. Med. Int. Health.* 2021; 26(8): 862–81. <https://doi.org/10.1111/tmi.13600>
  23. Food and Drug Supervisory Agency. Guidelines for follow-up results of Drug Control, drug ingredients, narcotics, psychotropics, precursors, and addictive substances. Indonesia; 2024; (9). (in Indonesian)
  24. Khomsiyah, Zamroni M., Adriano. Legal consequences of selling antibiotics drugs without doctor's prescription in pharmacies. *JILPR*. 2024; 6(1): 22–31. <https://doi.org/10.56371/jirpl.v6i1.302>
  25. Sachdev C., Anjankar A., Agrawal J. Self-medication with antibiotics: an element increasing resistance. *Cureus*. 2022; 14(10): e30844. <https://doi.org/10.7759/cureus.30844>
  26. Uddin T.M., Chakraborty A.J., Khusro A., Zidan B.R.M., Mitra S., Emran T.B., et al. Antibiotic resistance in microbes: History, mechanisms, therapeutic strategies and future prospects. *J. Infect. Public Health.* 2021; 14(12): 1750–66. <https://doi.org/10.1016/j.jiph.2021.10.020>
  27. Sharma A., Singh A., Dar M.A., Kaur R.J., Charan J., Iskandar K., et al. Menace of antimicrobial resistance in LMICs: Current surveillance practices and control measures to tackle hostility. *J. Infect. Public Health.* 2022; 15(2): 172–81. <https://doi.org/10.1016/j.jiph.2021.12.008>
  28. Phalke V., Phalke D.B., Durgawale P.M. Self-medication practices in rural Maharashtra. *Indian J. Community Med.* 2006; 31(1): 34–5. <https://doi.org/10.4103/0970-0218.54933>
  29. Godman B., Egwuenu A., Haque M., Malande O.O., Schellack N., Kumar S., et al. Strategies to improve antimicrobial utilization with a special focus on developing countries. *Life (Basel)*. 2021; 11(6): 528. <https://doi.org/10.3390/life11060528>
  30. Torres N.F., Solomon V.P., Middleton L.E. Pharmacists' practices for non-prescribed antibiotic dispensing in Mozambique. *Pharm. Pract. (Granada)*. 2020; 18(3): 1965. <https://doi.org/10.18549/PharmPract.2020.3.1965>
  31. Abilova V., Kurdi A., Godman B. Ongoing initiatives in Azerbaijan to improve the use of antibiotics; findings and implications. *Expert Rev. Anti Infect. Ther.* 2018; 16(1): 77–84. <https://doi.org/10.1080/14787210.2018.1417835>
  32. Fürst J., Čižman M., Mrak J., Kos D., Campbell S., Coenen S., et al. The influence of a sustained multifaceted approach to improve antibiotic prescribing in Slovenia during the past decade: findings and implications. *Expert Rev. Anti Infect. Ther.* 2015; 13(2): 279–89. <https://doi.org/10.1586/14787210.2015.990381>
  33. Bojanić L., Marković-Peković V., Škrbić R., Stojaković N., Đermanović M., Bojanić J., et al. Recent Initiatives in the Republic of Srpska to enhance appropriate use of antibiotics in ambulatory care; their influence and implications. *Front. Pharmacol.* 2018; 9: 442. <https://doi.org/10.3389/fphar.2018.00442>
  34. Wojkowska-Mach J., Godman B., Glassman A., Kurdi A., Pilc A., Rozanska A., et al. Antibiotic consumption and antimicrobial resistance in Poland; findings and implications. *Antimicrob. Resist. Infect. Control.* 2018; 7: 136. <https://doi.org/10.1186/s13756-018-0428-8>

**Information about the author**

Ajeng Illastria Rosalina, Master, S. Farm., Apt., M. Farm. Manager Indonesian FDA Regional Office in Jakarta, 13870, Jakarta, Republic of Indonesia, <https://orcid.org/0000-0001-6184-4803> E-mail: ajengrosalyne.air@gmail.com

**Информация об авторе**

Адженг Иллэстрия Розалина, Магистр, С. Фарм., Апт., М. Фарм. Менеджер индонезийского регионального офиса FDA в Джакарте, 13870, Джакарта, Республика Индонезия. E-mail: ajengrosalyne.air@gmail.com