LEGAL CONSEQUENCES OF SELLING ANTIBIOTICS DRUGS WITHOUT DOCTOR'S PRESCRIPTION IN PHARMACIES

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Abstract

The use of antibiotic drugs is subject to statutory regulations, which require a doctor's prescription for purchase. Antibiotic drugs are classified as "list G drugs" or "hard drugs," and they can only be submitted with a doctor's prescription. The objective of this investigation is to examine the legal liability of pharmacies as sellers of antibiotics without a doctor's prescription and the legal repercussions for purchasers of antibiotics without a prescription. This research employs a form of normative legal research. This research employs a normative legal research method that employs primary data sources and secondary data, or data obtained through a statutory and conceptual approach. The results of this study are that the Pharmacist, as a pharmacy supervisor, is fully responsible for the delivery and collection of drugs to prevent unwanted events. Patients will not receive legal protection if they fail to comply with the Pharmacist's instructions to refrain from purchasing antibiotics without a doctor's prescription.

Keyword: Legal Effects, Legal Liability, Antibiotics, and Pharmacies

INTRODUCTION

Supervising the distribution of drugs is one of the greatest challenges in overseeing the drug supply chain, which encompasses an integrated system that includes the flow of products from suppliers, manufacturers, and retailers to the end consumer. It involves a connection between supervision segments, including pharmaceutical industries, large pharmaceutical traders (PBF), healthcare facilities, and retailers before drugs reach consumers or patients (Li et al., 2024; Yovia et al., 2021).

Drug distribution within the commodity trade falls under the scope of pharmaceutical practices, as regulated by Law Number 17 of 2023 concerning Health (Health Law), specifically Article 145, which states: "Pharmaceutical practices must be carried out by pharmaceutical personnel in accordance with the provisions of laws and regulations stipulated by the government to ensure the safety, quality, and efficacy of drugs until they reach society or patients." Additionally, Article 143 of the Health Law stipulates that: "Anyone who manufactures and/or distributes Pharmaceutical Preparations or Medical Devices must obtain a business license from the central or regional government in accordance with their authority, based on norms, standards, procedures, and criteria as regulated by laws and regulations."

In practice, violations are often found in the drug distribution process, particularly when there are facilities employing unqualified or unauthorized personnel. These violations result in supply chain diversions, as monitoring the distribution channels is difficult. Drug distribution can occur both inside and outside the network. Outside the network, violations include the sale of controlled drugs at unauthorized facilities and drug stores without a prescription. Inside the network, as a result of Industry 5.0 advancements, drug distribution can occur through e-commerce, social media, or personal portals (Waluyo et al., 2021; Yovia et al., 2021)

One specific distribution violation is the sale of antibiotics without a doctor's prescription, particularly in pharmacies. This has become a global issue. Data from the Centers for Disease Control and Prevention (CDC) in the United States reveals that there are around 50 million unnecessary antibiotic prescriptions each year. Similarly, in Indonesia, 495 visits to pharmacies and private drug stores in 2021 revealed that in 70% of these visits, antibiotics were dispensed without a prescription (Dewi & Juliadi, 2021; Mailuhuw et al., 2023; Nurrohmah & Hufron, 2023)

Antibiotics are commonly prescribed for patients, but their misuse frequently occurs due to the public's lack of knowledge and understanding about proper and rational antibiotic use. According to the Law on Controlled Drugs (St. No. 419, December 22, 1949) (Law on Controlled Drugs), Article 3 paragraph (2) states:

"The dispensing of G materials without a prescription from a Doctor, Dentist, or Veterinarian is prohibited. This prohibition does not apply to dispensing to recognized large traders, pharmacists, dentists, and veterinarians, nor to the dispensing according to the provisions of Article 7 paragraph 5."

Antibiotics are classified as controlled drugs (G list drugs) that may only be prescribed by doctors, dentists, or veterinarians (Epstein et al., 2000; Guerrini et al., 2019). The term "G" comes from the Dutch word "gevarrlijk," meaning dangerous. These drugs, if misused or uncontrolled, can exacerbate diseases, poison the body, or even cause death.

The dispensing and distribution of medications are the full responsibility of the pharmacist, who acts as the supervisor in pharmacies to ensure that no adverse events occur. Pharmacists are required to procure medications and verify doctors' prescriptions before dispensing them to consumers, ensuring that the dosage and type of medication provided align with the prescription. Additionally, they are responsible for providing information and education regarding the correct and safe use of medications. Government Regulation No. 51 of 2009 on Pharmaceutical Practices (PP 51/2009), Article 21(2), stipulates that "the dispensing and provision of medications based on a doctor's prescription must be carried out by a

pharmacist." Furthermore, Article 20 of the same regulation states that in the execution of pharmaceutical services within pharmaceutical service facilities, pharmacists may be assisted by assistant pharmacists and/or pharmaceutical technicians, but the ultimate responsibility remains with the pharmacist.

The supervision of medications is facilitated by the National Agency of Drug and Food Control (BPOM), which is designated by the government to oversee the regulation of drugs and food, as outlined in the Joint Decree of the Minister of Health of the Republic of Indonesia and the Minister of Administrative Reform of the Republic of Indonesia No. 264A/MENKES/SKB/VII/2003 and No. 02/SKB/M.PAN/7/2003, concerning the Duties, Functions, and Authority in the Field of Drug and Food Supervision.

The provision of controlled medications without a doctor's prescription is also influenced by the involvement of the community, where individuals often engage in self-medication. Factors such as ease of transactions, time and energy efficiency, lifestyle changes, and the public's limited knowledge of drug side effects and self-medication guidance lead to inappropriate medication use, resulting in undesirable effects.

The objective of this article is to evaluate the legal responsibility of pharmacies as sellers of antibiotics without a doctor's prescription and to evaluate the legal repercussions for individuals who purchase antibiotics without a prescription at pharmacies, as outlined in the aforementioned background.

RESEARCH METHOD

This study employs a normative legal research methodology, utilizing both primary and secondary data through statutory and conceptual approaches. The statutory approach involves examining laws relevant to the legal issues at hand, with a particular focus on identifying gaps or deviations in regulatory implementation (Ali, 2021; Sidharta, 2009; Syahrum, 2022). The conceptual approach incorporates legal doctrines and viewpoints to construct legal arguments. The legal materials used in this research include primary sources, such as legislation, regulatory drafting records, and judicial decisions, as well as secondary materials obtained through literature review (Marzuki, 2021). The analysis of these legal materials is conducted using a descriptive qualitative method, which refers to legal norms found in legislation, judicial rulings, and societal norms. The research process involves organizing, interpreting, and analyzing findings from a specific perspective, presenting them descriptively in a narrative format that aligns with the research problem being addressed.

RESULT AND DISCUSSION

Obligations of Antibiotic Buyers at Pharmacies to Comply with Drug Purchase Regulations

A 2015 World Health Organization (WHO) study of 12 low- and middle-income countries (LMICs) revealed that 93% of patients obtained antibiotics from drugstores and pharmacies, leaving only a small fraction who acquired them directly from healthcare professionals. Many LMIC patients view small drugstores and community pharmacies as their first, more accessible option for obtaining healthcare services for common illnesses and, crucially, antibiotics. Health-seeking behavior is defined as any action taken by an individual who perceives themselves as having a health issue, with the goal of finding appropriate treatment (Do et al., 2021; Torres et al., 2019)

According to the Health Law, under the Second Part on Obligations, Article 5 Paragraph (1) states: “Everyone is obliged to: a. achieve, maintain, and improve the highest possible degree of public health; b. protect and enhance the health of others under their responsibility; c. respect others' rights in obtaining a healthy environment; d. adopt healthy

living behaviors and respect the health rights of others; e. comply with epidemic or outbreak control activities; and f. participate in the national social security health program."

Paragraph (2) explains that "the obligations under paragraph (1) letter a include: a. individual health efforts; b. public health efforts; and c. health-oriented development." Furthermore, Paragraph (3) clarifies that "the obligation to participate in the health insurance program under paragraph (1) letter f is carried out in accordance with applicable regulations." Article 18 Paragraph (1) of the Health Law also specifies that "individual health efforts, as referred to in Article 17 Paragraph (2), include promotive, preventive, curative, rehabilitative, and/or palliative efforts affecting individuals." Paragraph (2) adds that "public health efforts, as referred to in Article 17 Paragraph (2), include promotive, curative, rehabilitative, and/or palliative efforts affecting the community."

Health refers to a state of well-being physically, mentally, and socially, beyond merely being free from disease, enabling individuals to live productive lives. Health services encompass all forms of direct services provided to individuals or communities, including promotive, preventive, curative, rehabilitative, and/or palliative care (Boorse, 1977; Vázquez et al., 2009)

The right to health is recognized as a fundamental human right in both international and national instruments. It is a basic human need that cannot be diminished under any circumstances. The General Comment No. 14 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) underscores that the right to health is a fundamental and invaluable human right, essential for realizing other human rights. As such, ensuring access to health is guaranteed as a human right in various international and national legal frameworks.

The right to health is intrinsically linked to human survival, as it pertains to the availability of healthcare services, medications, a clean and healthy environment, and other factors essential for sustaining human life. The state's obligation to fulfill the right to health for its citizens is recognized in both international and national legal instruments. The Universal Declaration of Human Rights (UDHR), adopted on December 10, 1948, was the initial declaration that included the right to health as part of human rights. The WHO Constitution, established on April 7, 1948, further emphasizes, "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions." This indicates that every person has the fundamental right to the highest attainable standard of health, irrespective of race, religion, political belief, or socio-economic status.

Article 12 of the ICESCR states that "everyone has the right to enjoy the highest attainable standard of physical and mental health." This provision emphasizes that health is an individual right, and the highest achievable standard reflects each person's enjoyment of this right. At the national level, Article 28H of the 1945 Constitution of Indonesia states, "Every person has the right to live in physical and mental well-being, to have a place to live, and to obtain a good and healthy living environment, and has the right to health services." This provision highlights the shift in the health paradigm, whereby health is recognized as an individual right, but its fulfillment is the responsibility of the state.

The responsibility of the state to fulfill, protect, and respect human rights is mandated by Indonesia's Human Rights Law No. 39 of 1999 (UU HAM) and the 1945 Constitution. These principles are also reflected in international human rights covenants and conventions. Three main obligations bind states that ratify international human rights treaties:

a) Obligation to Respect
b) Obligation to Fulfill
c) Obligation to Protect

Upon ratifying the ICESCR, states are obligated to fully implement their constitutional duty to promote the well-being of their people. This is reinforced by General Comment No. 3, which

mandates states to formulate concrete steps to improve the fulfillment and protection of the economic, social, and cultural rights of their citizens. In line with General Comment No. 3, states have a primary obligation to guarantee the realization of these rights, including under Article 12 of the ICESCR. General Comment No. 14 elaborates on core obligations, such as:

a) Ensuring non-discriminatory access to healthcare facilities, goods, and services, particularly for vulnerable and marginalized groups.
b) Ensuring access to essential, nutritionally adequate, and safe food, preventing hunger for every individual.
c) Ensuring access to basic housing, sanitation, and sufficient and safe water supplies.
d) Providing essential medicines as defined by the WHO's Action Program on Essential Drugs.
e) Ensuring the equitable distribution of healthcare facilities, goods, and services.

The Right to Health in the International Covenant on Economic, Social, and Cultural Rights (ICESCR) Article 12 of the ICESCR recognizes that:

1) States Parties to this Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
   a. The reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
   b. The improvement of all aspects of environmental and industrial hygiene;
   c. The prevention, treatment, and control of epidemic, endemic, occupational, and other diseases;
   d. The creation of conditions which would assure to all medical services and medical attention in the event of sickness.

According to the WHO, several determinants of health exist, including social, economic, and physical environments, as well as individual characteristics and behaviours (Casellas et al., 2002; Sobhonslidsuk et al., 2006). These include:

1. Socio-economic Status
   Higher income and social status positively influence health access, which explains the significant disparity between the wealthy and the poor in health outcomes
2. Education
   Lower education levels correlate with poorer health, stress, and reduced self-confidence.
3. Physical Environment
   A healthy physical environment, including clean air, water, and safe workplaces, contributes to overall health.
4. Social Support Networks
   Support from family, friends, and community influences health outcomes. Cultural traditions, values, and beliefs also play a role in shaping health behaviors.
5. Genetics
   Genetic factors affect life expectancy, health, and certain diseases. External factors like smoking, drinking, and coping with stress also influence health.
6. Healthcare Services
   Access to and use of healthcare services prevent and treat diseases that impact health.
7. Gender
   Different genders, whether male or female, may experience different vulnerabilities to certain diseases at various stages of life.

Based on the identification of various issues in the healthcare sector, such as the predominance of curative approaches in healthcare services, the availability and distribution of health resources, preparedness for health crises, the self-reliance of the pharmaceutical and medical device industries, financial aspects, and the utilization of health technologies, a transformation of the healthcare system has been undertaken. The implementation of this healthcare system transformation requires a strong and comprehensive regulatory framework to address these diverse healthcare challenges.

Medications play a crucial role in public health, as they are essential for treating diseases affecting humans. One such category of drugs is antibiotics, which are used to eliminate bacteria in the body and enhance immune function. According to the provisions of the Ministry of Health Regulation No. 73 of 2016 on Pharmaceutical Service Standards, and Decree No. 02396/A/SK/VIII/1986 on Special Labels for G-list Controlled Drugs, antibiotics, classified as G-list controlled drugs, can only be dispensed with a valid doctor's prescription. However, in practice, antibiotics are often sold freely without a prescription by pharmacies, which violates consumer rights as stipulated in the Consumer Protection Act (UUPK), Article 4(a), which guarantees "the right to comfort, safety, and security in consuming goods and/or services." Furthermore, Article 7(b) of the UUPK states that "business actors are obligated to provide accurate, clear, and honest information regarding the condition and guarantees of goods and/or services, as well as provide instructions on their use, maintenance, and repair." In this context, pharmaceutical personnel in pharmacies must provide clear education to buyers regarding the use of antibiotics. If a consumer seeks to purchase antibiotics, it is the responsibility of the pharmacy to thoroughly and clearly explain that antibiotics require a doctor's prescription, rather than prioritizing profit and neglecting consumer safety.

The legal liability imposed on pharmacies is based on negligence. As such, pharmacies are required to compensate consumers (buyers) if their negligence causes harm to the buyer due to the misuse of antibiotics, which can result in overdose, resistance, or even death.

The rational and cautious use of antibiotics, as regulated by the Ministry of Health's Antibiotic Regulation, refers to the careful consideration of the risks of the emergence and spread of antibiotic-resistant bacteria. This approach, known as antibiotics stewardship, aims to improve patient outcomes in a coordinated manner by enhancing the quality of antibiotic use. Key steps in this approach include ensuring accurate diagnosis to ensure antibiotics are only used when necessary, selecting the appropriate type of antibiotic for a specific infection, determining the effective dose without causing side effects, setting the correct interval between doses to maintain drug effectiveness in the body, choosing the optimal route of administration, such as oral or injection, and determining the appropriate duration of use to ensure the infection is fully treated without unnecessarily prolonging the course of treatment, which could lead to resistance. The ultimate goal is to prevent the misuse and overuse of antibiotics, thereby avoiding the development of antibiotic resistance while ensuring that patients receive effective and safe treatment.

The legal consequences for purchasing antibiotics at a pharmacy without a doctor's prescription

Legal consequences arise from the existence of a legal relationship, which confers rights and obligations established by law. Violations of these legal obligations can lead to legal action being taken against the violator in court.

The relationship between a pharmacist and a patient, from a legal perspective, can be classified as a special legal relationship. This is because pharmacists are obligated to enhance the quality of patient care, whether it is in promotive, preventive, curative, or rehabilitative aspects, based on transactions involving drug services. The legal objective is to protect both public and individual interests from unpleasant actions resulting from violations. The law aims

to strike a balance between protecting societal and individual interests, reflecting a more holistic view rather than an individualistic one (Irawan et al., 2023).

According to the Minister of Health Regulation No. 73/2016, Article 1, Clause 3, "Pharmaceutical service is a direct and responsible service to patients related to pharmaceutical preparations with the aim of achieving definite results to improve the quality of life of the patient." Article 4, Clause (1) states, "The implementation of pharmaceutical service standards at pharmacies must be supported by the availability of pharmaceutical resources oriented towards patient safety," and Article 6 stipulates, "The provision of pharmaceutical services at pharmacies must ensure the availability of pharmaceutical preparations, medical devices, and consumable medical supplies that are safe, of high quality, beneficial, and affordable."

According to Minister of Health Regulation No. 73/2016, the development of science and technology in the pharmaceutical field has led to a shift in the orientation of pharmaceutical services from the management of drugs as commodities to comprehensive pharmaceutical care. This broader perspective includes providing information to support the correct and rational use of medications, monitoring drug use to achieve intended outcomes, and identifying potential medication errors.

In the context of health law, Article 320, Clause (1) of the Health Law states, "Medicines consist of: a. Prescription medicines; and b. Non-prescription medicines." Clause (3) specifies, "Prescription medicines are provided by pharmacists at pharmaceutical service facilities according to legal provisions," and Clause (6) states, "Non-prescription medicines are obtained from pharmaceutical service facilities or other facilities according to legal provisions."

Antibiotics fall under the category of controlled medications listed in Category G, which must be used based on a doctor's prescription, as specified in the Minister of Health Regulation on Antibiotics, Article 3: "The use of antibiotics must be based on a doctor's or dentist's prescription according to legal provisions."

Medications that can only be purchased with a doctor's prescription cannot be dispensed without one. For antibiotics, if regulations specify that they must be purchased with a prescription, pharmacies are obligated to comply. Compliance with legal regulations is mandatory for all citizens. If a patient insists on purchasing antibiotics without a prescription, despite receiving education on their use, the patient will not receive legal protection (Asmara, 2021).

The transaction between a pharmacy and a consumer can be categorized as a contract. The legal consequences of such a contract can include performance of obligations or the right to receive performance. For a contract to be valid under Article 1320 of the Civil Code, four conditions must be met: 1. Mutual agreement of the parties involved; 2. Capacity to enter into a contract; 3. A specific subject matter; 4. A lawful cause. A contract made between a pharmacy and a consumer is valid under the Civil Code if it adheres to these conditions. However, if the sale of antibiotics occurs through a contract for antibiotics without a prescription, it violates the fourth condition—lawful cause—since such a sale contravenes legal provisions, which require that controlled medications like antibiotics be dispensed only with a prescription.

The sale of antibiotics involves two legal subjects: the seller (pharmacy) and the buyer (consumer). The buyer must present a prescription signed by a doctor or a copy of the prescription signed by a pharmacist and be able to pay for the medication. Presenting a prescription is mandatory because antibiotics are controlled substances that can pose health risks if misused (Ferdiana et al., 2021).

Criminalization concepts may serve as a basis for law enforcement regarding buyers of controlled medications without a prescription, as part of ius constituendum, which refers to legal concepts governing the criminalization of such behavior. The criminalization of buyers of controlled substances without a prescription is a controversial issue within the realm of ius

constituendum. Supporters argue that it protects public health and safety. Criminalization acts as a deterrent against the unauthorized acquisition of controlled substances, providing legal legitimacy to address such violations. However, this can impose additional burdens and fears on individuals who need controlled medications but are reluctant to consult a doctor. Consequently, the criminalization of purchasing controlled medications without a prescription may create uncertainties for the government and conflict with human rights considerations.

The solution to this issue currently available to the government involves enhancing public education and awareness regarding the dangers of purchasing controlled medications without a prescription. This is part of the government's effort to make health check-ups with doctors a crucial step before purchasing medications. Pharmacies also play a significant role. In addition to governmental educational and awareness initiatives, pharmacies must hold appropriate licenses and adhere to established pharmaceutical regulations. The government must increase oversight of pharmacies that dispense controlled medications without prescriptions and impose strict sanctions in cases of non-compliance.

Patients who purchase antibiotics from pharmacies without a prescription, despite being informed and instructed by pharmacists, are responsible for any legal consequences resulting from their decisions. According to the Indonesian Minister of Health Regulation No. 4 of 2018 concerning the rights and obligations of patients, Article 26, letter g, "Patients must accept all consequences of their personal decision to refuse the recommended therapy plan from health workers and/or to not follow the instructions given by health workers for the treatment of their illness or health issue."

Furthermore, Article 8, Clause (1), letter d, of the Consumer Protection Law (UUPK) states that "Business actors are prohibited from producing and/or trading goods and/or services that: d. do not comply with the conditions, guarantees, special characteristics, or efficacy stated on the label, tag, or description of the goods and/or services." This implies that business operators, including pharmacies, must inform consumers that antibiotics, being controlled medications, must be purchased with a doctor's prescription. Failure to do so could result in adverse effects such as gastrointestinal disturbances, drug allergies, drug resistance, and even death.

Pharmacies are required to sell controlled medications in accordance with established procedures. They must refuse sales of such medications without a prescription and report each sale to the Health Department. This reporting requirement is established by health authorities to prevent unauthorized purchases of controlled medications. Pharmacies failing to report the sale of controlled substances may face sanctions from the Health Department, ranging from warnings to business license revocation. Local governments, in collaboration with the National Agency of Drug and Food Control (BPOM), are also responsible for overseeing the purchase and sale of medications within the community.

BPOM, as a non-departmental government agency, has the mandate to oversee drug and food safety in accordance with applicable regulations. BPOM, headquartered in Jakarta, operates through regional technical implementation units. BPOM’s responsibilities include implementing policies related to the supervision of therapeutic products, narcotics, psychotropics, other addictive substances, traditional medicines, complementary products, food safety, and hazardous materials. Consequently, the supervision of pharmacies as providers of therapeutic products is a key responsibility of BPOM in each region.

According to BPOM Regulation No. 24 of 2021, Article 10, "In order to oversee the management of drugs, drug materials, narcotics, psychotropics, and pharmaceutical precursors, BPOM conducts monitoring, provides technical guidance, and supervises pharmaceutical service facilities." BPOM plays a crucial role in monitoring the circulation of antibiotics, especially in pharmacies, as excessive use can lead to economic and clinical issues such as antibiotic resistance.

BPOM's oversight, as outlined in Article 11, Clause (1), includes inspections conducted by officers. Clause (2) grants officers the authority to: a. Enter any premises suspected of being used for managing drugs, drug materials, narcotics, psychotropics, and pharmaceutical precursors to inspect, examine, and collect samples of such items; b. Open and inspect the packaging of these items; c. Examine documents or records suspected of containing information about the management of these substances, including duplicating or quoting such information; and/or d. Take photographs or images of the facilities and equipment used in the management of these substances.

Clause (3) specifies that oversight should be coordinated with relevant agencies in accordance with legal provisions. Clause (4) states that any individual responsible for the inspection site may refuse the inspection if the officers are not equipped with a written order and identification. Clause (5) allows for further provisions on oversight to be established by the Head of the Agency.

Health oversight is also regulated by the Health Law, Article 421, Clause (1), which mandates that "The Central and Regional Governments conduct oversight of all health services." Clause (2) outlines the scope of this oversight, which includes: a. Compliance with legal regulations, including adherence to norms, standards, procedures, and criteria set by the Central Government; b. Compliance with professional standards, service standards, standard operating procedures, and professional ethics and discipline; c. Impact of health services provided by medical personnel; d. Evaluation of public satisfaction; e. Accountability and adequacy of health efforts and resources; and f. Other areas of oversight as needed.

Clause (3) allows for community involvement in oversight. Article 422 permits the Central or Regional Government to enlist oversight personnel to assist in this process, in accordance with legal provisions.

CONCLUSION

Pharmacies are legally responsible for the sale of antibiotics without a prescription, but the issue is complex. Legal sanctions may not be applicable to individual-operated pharmacies, as these establishments are not legally accountable in the same way as other entities, as they operate with private capital. Conversely, a pharmacy that is operated by a non-individual entity, such as a foundation, limited liability company, or cooperative, may be subject to legal sanctions due to its status as a legal entity. A pharmacist is personally liable if an error is made in compounding medication according to a prescription, resulting in a consumer's claim. This responsibility is also specific. In contrast, the director of the pharmacy is accountable for any losses that result from errors in bookkeeping.

A consumer's rights will be forfeited if they purchase antibiotics at a pharmacy without a prescription. The pharmacy is legally prohibited from dispensing antibiotics without a prescription if they are legally required to be dispensed exclusively with one. Legal protection will not be provided to a consumer who disregards the pharmacist's instruction and purchases antibiotics without a prescription.

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