


Article Review: Analysis of Regulation and Implementation of Sale of Strict Drugs Without Prescription in Pharmacies: Literature Review

Irnaily Sabilla Elleny Subing

Pharmacy Study Program, Faculty Medicine, University of Lampung, Indonesia

Article Info	ABSTRACT
<p>Keywords: Prescription drugs, prescription doctor, pharmacy, supervision, regulation</p>	<p>The sale of prescription drugs without a doctor's prescription remains a common issue in many pharmacies, despite clear regulations prohibiting such practices. This article is a narrative literature review aimed at analyzing the legal framework, pharmacist accountability, and the effectiveness of supervision concerning the distribution of prescription-only medicines in Indonesia. The review is based on five relevant scientific articles and a selection of applicable legal regulations. Findings show that regulatory loopholes, weak enforcement of administrative sanctions, and low public awareness regarding appropriate drug use contribute to ongoing violations. Furthermore, the rise of online pharmacies and the ease of accessing drugs through digital platforms exacerbates the risk of misuse. Therefore, it is essential to strengthen adaptable regulatory frameworks, enhance public education, and develop an integrated supervision system, including the use of digital verification technologies.</p>
<p>This is an open access article under the CC BY-NC license</p> 	<p>Corresponding Author: Irnaily Sabilla Elleny Subing Pharmacy Study Program, Faculty Medicine, University of Lampung, Indonesia gheafantika@gmail.com</p>

INTRODUCTION

Health is right base every guaranteed individual in the Indonesian constitution, as listed in Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia. For realize degrees optimal health, one of aspect crucial is regulation and supervision to use drug hard that only may given on recipe doctor. However, in in practice, sales drug hard without recipe Still Lots found in various regions in Indonesia, including in facilities official like pharmacy.

The problem This the more complex with the development of digital trading platforms (e-commerce), which opens up gap for distribution drug hard without supervision adequate. Kompas' report in March 2024 revealed that a number of online pharmacy sells antibiotics reserve type such as meropenem without verification valid recipe. In some case, system verification Can passed by only with attach picture haphazard like newspaper, which remains accepted by the system online sales. Conditions This of course it is very worrying remember abuse drug hard can cause effect side serious, aggravate disease, even cause resistance antimicrobial.

In the study field in Banda Aceh by Siregar and Darmawan (2023), found that low understanding public about classification drug be one of reason main purchase without recipe. In addition, the desire to obtain drug in a way fast and cheap make consumer ignore procedure correct medical. While that, in Lebak Regency, research by Septianingsih et al. (2024) showed that pharmacist Still many ignore regulation Because weakness supervision from party authorities, including BPOM and the service health local.

In general normative, regulatory about sale drug hard has set up in various regulation like Law No. 17 of 2023 concerning Health, Regulations Government Regulation No. 51 of 2009 concerning Work Pharmacy, as well as Minister of Health Regulation No. 9 of 2017 concerning Pharmacy. All regulation the confirm that drug hard No may handed over without recipe a legitimate doctor. However, the weakness implementation and supervision cause mismatch between rule written and the reality on the ground.

Based on condition said, article This arranged as study literature For review in a way critical regulations that govern sale drug hard at the pharmacy, evaluating not quite enough answer law pharmacist, and to examine effectiveness supervision government. The method used is studies library based on approach legal normative and empirical, with analyze five articles relevant scientific, published in range 2023–2025. Through review this, it is expected can formulated strategies and recommendations capable policy close gap regulation and strengthening compliance in practice pharmacy in Indonesia.

METHOD

This article arranged with narrative literature review approach, namely the method used For compile study based on library with objective explore and analyze in a way deep various source relevant scientific with Topic. Approach This considered in accordance Because capable give description intact about framework law, implementation in the field, and not quite enough answer profession related sale drug hard without recipes in Indonesia.

Search literature done in a way systematic against five articles published scientific in range 2023 to 2025. Criteria election includes : (1) article must discuss Topic laws and regulations distribution drug hard without recipe ; (2) contains element analysis to practice in the field, both in form studies empirical and normative ; and (3) derived from from source credible, such as journal accredited national or institution education tall.

In addition to the article scientific, data sources also include regulations in force in Indonesia, including the Law Number 17 of 2023 concerning Health, Law Number 8 of 1999 concerning Protection Consumers, Regulations Government Number 51 of 2009 concerning Work Pharmacy, as well as a number of regulation technical from the relevant Ministry of Health and Food and Drug Supervisory Agency (BPOM).

Every source analyzed in a way descriptive-qualitative, with identify the main points discussion, findings main, and point similarities and differences between reference. Analysis done with approach conceptual and statutory approach to understand Good base law and its implementation in context service pharmacy in Indonesia. With method this, article aiming serve synthesis comprehensive from existing literature, at the same time submit thinking

critical and alternative solution to weakness implementation regulation sale drug hard without the recipe is still Lots found in the field.

RESULT AND DISCUSSION

Research result

Table 1. Legal Basis for Sanctions Violation Sales of drugs above HET.

No	Title, Author, and Year	Legal basis	Research methods	Conclusion
1	Administrative Legal Responsibility Pharmacy to Sales of Hard Drugs Without Doctor's prescription Eka Septianingsih, written by Siti Rukiah, and written by Sri Dewi Agustina (2024).	PP No. 51 of 2009, Minister of Health Regulation No. 73 of 2016, Health Law No. 36 of 2009	approach legal normative & study field (Lebak Regency)	Many pharmacies still sell drug hard without recipe Because weakness supervision. Pharmacist Not yet operate not quite enough answer administration optimally.
2	Hard Drugs Without Doctor's Prescription in Civil Law Review and Protection Consumer Andi Siregar & Dwi Darmawan (2023)	Law No. 8 of 1999 concerning Protection consumer	Legal empirical (Banda Aceh)	Sale drug hard without recipe violate right consumers and endanger safety patient. Low literacy society and its weaknesses supervision to worsen problem.
3	Legal Responsibilities of Pharmacists to Administration of Strong Drugs Without Doctor's Prescription at Facility Service Pharmacy. Sony Tresnadi, Maura Linda, Ahmad Makbul (2025)	Law No. 17 of 2023, Minister of Health Regulation No. 3 of 2021	Normative Juridical Law	Normative Pharmacist who submits drug hard without recipe can charged sanctions administrative and criminal. Need strengthening code ethics and enforcement law.
4	Sale Antibiotics without Doctor's Prescription in the Era of E-Commerce in Indonesia	Law No. 17 of 2023, ITE Law, Presidential Decree No. 49 of 2024, BPOM No. 14 of 2024	Narrative literature review	Practice sale antibiotics online without recipe Still rampant. System online verification is weak and vulnerable manipulation.

	PM Afladhanti, et al. (2024)			Recommended use OCR and NLP technology for control recipe.
5	Enforcement Regulation Sale Antibiotics in E-Commerce: Legal Studies and Digital Solutions 2024 MHKI Congress Article – Afladhanti et al.]	1945 Constitution, 2023 Health Law, ITE Law, Presidential Decree No. 49 of 2024	Narrative review + analysis policy	Need strengthening regulation sale antibiotics online, the use of AI in verification recipes, as well as synergy between government, e-commerce providers, and workforce pharmacy.

Discussion

Regulation Sales of Hard Drugs in Indonesia

Sale drug hard in Indonesia has set up in a number of regulation legislation. Law Number 17 of 2023 concerning Health in general firm to mention that drug hard only can handed over on base recipe doctor. Terms This emphasized in Article 320 paragraph (5), which states that only drug certain that may given without prescription by pharmacist, according to regulation more carry on.

Temporary that, the rules Government Number 51 of 2009 concerning Work Pharmacy and the Minister of Health Regulation Number 9 of 2017 confirms that every pharmacist must operate service appropriate pharmacy with provision ethics and law, including in the process of submission drug hard. In addition, Law Number 8 of 1999 concerning Protection Consumer give runway law additionally, with emphasize that perpetrator business including pharmacy must give product in accordance standard and not may endanger consumers. Regulations the Actually Already Enough comprehensive. However, the weakness implementation in the field make violation to rule This Still often happen.

Facts of Violations in the Field

A number of studies reviewed show that practice sale drug hard without recipe doctor Still Lots occurs in various area. Research conducted in Banda Aceh by Siregar and Darmawan (2023) revealed that a number of pharmacy sell drug like glibenclamide, amoxicillin, and clobetasol without request recipe doctor. Findings Similar findings were also found by Septianingsih et al. (2024) in Lebak Regency, which showed that violation This No things that are incidental, but Already become repeated practice.

Trend this is also compounded by convenience access purchase drug online. The article by Afladhanti et al. (2024) states that on various e-commerce platforms, buyers can with easy access antibiotics without through the verification process valid recipe. In fact, in national media investigation, found that system verification can with easy manipulated, such as with attach picture No relevant as a “ recipe ” that remains accepted by the system. Violation This show existence gap in system supervision as well as low compliance to ethics profession.

Legal Responsibilities of Pharmacists

In practice, pharmacists own not quite enough answer sufficient law big in every actions taken related service medicine. Based on study conducted by Tresnadi et al. (2025), pharmacist who handed over drug hard without recipe can charged sanctions administrative and criminal, depending on the level violations. The 2023 Health Law even to list threat criminal up to five years prison and fine maximum five hundred million rupiah for the party that is illegal deliver stock pharmaceuticals, including drug hard. However in in practice, enforcement to violation This Not yet fully walk effective. Pharmacist often reasonable that sale done Because pressure consumers, habits in the environment work, or Because No existence strict supervision from authority local.

Challenges Supervision and Implementation Regulation

A number of challenge main in implementation supervision to distribution drug hard among others: limitations amount supervisor in the field, not yet optimal system reporting by pharmacies, as well as Not yet the existence of an integrated national platform For monitor distribution drug in real time. In online practice, weaknesses system verification recipes on e-commerce become gap big one yet closed in a way regulatory. Although Regulation Presidential Decree No. 49 of 2024 and BPOM No. 14 of 2024 have start touch supervision distribution online medicine, effectiveness its implementation Still questionable.

Strategy and Solution Recommendations

A number of literature recommend the need innovation in system supervision, including utilization digital technology for validation recipes. For example, the use of OCR (Optical Character Recognition) and Natural Language Processing (NLP) for scan authenticity recipe doctor in a way automatically, as highlighted in article Afladhanti et al. (2024). In addition, it is also necessary to improve education programs. society and actors business pharmacy about danger use drug hard without supervision medical. Strengthening function supervision by BPOM and the service health, training ethics and law for pharmacist, and improvement sanctions administrative in a way gradually also become part from solutions offered in literature.

Disconnection between Regulation and Implementation

Although in a way normative regulation related sale drug hard Already set up with Enough detailed, field practice show existence significant distance between rule written and its implementation. In a study conducted by Tresnadi et al. (2025), it was stated that existence regulation such as Law No. 17 of 2023 and PP No. 51 of 2009 only will effective If accompanied by with system strong supervision and sanctions are enforced in a way consistent. Unfortunately, many violations that are not followed up in a way law, especially in areas with supervision weak pharmacy.

A study by Septianingsih et al. (2024) even underline that in a number of pharmacy, violation happen in a way outright Because existence tolerance culture Work as well as pressure economy from owner business to pharmacist. That is, non-compliance No only question lack of understanding law, but also rooted in the system management pharmacy and low accountability in practice service pharmacy.

The role of e-commerce in Open Gap Violation

Digital platforms now be one of channel main distribution drug hard without recipe. The article by Afladhanti et al. (2024) shows that part big sale antibiotics through the marketplace no own system adequate verification. Even when condition upload recipe enforced, system the Still can passed by with uploads fake. This is reflect that existing digital systems Not yet built with runway verification strong medical.

Government Actually has start respond problem This through Regulation President Number 49 of 2024 and BPOM regulations that regulate supervision distribution drug online. However, the implementation Not yet touch system based control technology in a way comprehensive. On the other hand, adoption technology such as OCR and algorithms reader recipe automatic based on NLP mentioned by Afladhanti et al. (2024) to be offer interesting that can developed as solution term long.

Low Drug Education and Literacy

Second studies field from Siregar and Darmawan (2023) and Septianingsih et al. (2024) showed that that one of root from the rise purchase drug hard without recipe is low understanding public about classification medicine. Many patients do not know difference between drug free, medicine hard, and drugs that require supervision medical. As a result, society No feel that purchase without recipe is violation.

This matter become not quite enough answer double : first, at the pharmacist who should operate communication, information and education (KIE) to patients ; and secondly, to the government as a regulator for create system counseling more public massive and precise target. Unfortunately, in practice, education often neglected Because busyness service or pressure commercial in pharmacy.

Policy Recommendations and Solution Innovations

Almost all reviewed articles agree that strengthening system supervision is key. Some solutions offered includes :

1. Utilization technology digital verification : OCR and NLP systems for validate authenticity recipe in a way automatic before transactions on online platforms.
2. Improvement sanctions administrative and supervisory : Enforcement to violating pharmacy rule must enforced without exceptions, especially those operating online without supervision pharmacist still.
3. Campaign structured public, working The same with organization profession such as IAI (Association of Indonesian Pharmacist), service health, and media.
4. Service audit pharmacy in a way periodic : Checkup to pattern service, documentation recipe, and validity transactions by team supervisor independent.

Recommendation This No only demand repair regulation, but also change paradigm in practice service pharmacy and use technology in a way wise in system health.

CONCLUSION

Based on results study against five articles scientific and regulatory applicable legislation, can concluded that practice sale drug hard without recipe doctor Still become problem Serious in system service pharmacy in Indonesia. Although has there is sufficient regulation

comprehensive — such as Law Number 17 of 2023 concerning Health, PP Number 51 of 2009, and the Minister of Health Regulation related — its implementation in the field Still weak. Violation happen No only at the pharmacy conventional, but also increasingly expanding on e-commerce platforms that facilitate purchase drug without verification valid recipe. Factors like low supervision, weak sanctions law, pressure economy in pharmacy, as well as lack of literacy public about use drug become reason main practice This Keep going ongoing. Pharmacist as power health professional own role important in guard integrity service pharmacy, but in the practice often No operate not quite enough answer law optimally. This study also shows that challenge supervision No only nature structural, but also concerns technology, policy and culture work in the sector pharmacy.

REFERENCES

- Afladhanti, P. M., Umam, K., Rahmawati, T., & Mufidah, A. N. (2024). Tinjauan hukum penjualan antibiotik tanpa resep dokter di era e-commerce di Indonesia. Kongres MHKI VI. Universitas Islam Indonesia.
- Peraturan Presiden Republik Indonesia Nomor 49 Tahun 2024 tentang Strategi Nasional Perlindungan Konsumen.
- Peraturan Pemerintah Republik Indonesia Nomor 51 Tahun 2009 tentang Pekerjaan Kefarmasian.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 73 Tahun 2016 tentang Standar Pelayanan Kefarmasian di Apotek.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 3 Tahun 2021 tentang Klasifikasi dan Perizinan Obat Wajib Apotek (OWA).
- Peraturan Badan Pengawas Obat dan Makanan Republik Indonesia Nomor 14 Tahun 2024 tentang Pengawasan Obat dan Makanan yang Diedarkan secara Daring.
- Septianingsih, E., Rukiah, S., & Agustina, S. D. (2024). Tanggung jawab hukum administrasi apotek terhadap penjualan obat keras tanpa resep dokter. *Jurnal Kewarganegaraan*, 8(1), 8–12.
- Siregar, A. S., & Darmawan, D. (2023). Jual beli obat keras tanpa resep dokter dalam tinjauan hukum perdata dan perlindungan konsumen. *Jurnal Ilmu Mahasiswa Bidang Hukum Keperdataan*, 7(2), 214–222.
- Tresnadi, S., Linda, M., & Makbul, A. (2025). Tanggung jawab hukum apoteker terhadap pemberian obat keras tanpa resep dokter di fasilitas pelayanan apotek. *Jurnal Akademik: Mahasiswa Humanis*, 5(1), 169–179.
- Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan.
- Undang-Undang Republik Indonesia Nomor 8 Tahun 1999 tentang Perlindungan Konsumen.
- Undang-Undang Republik Indonesia Nomor 11 Tahun 2008 tentang Informasi dan Transaksi Elektronik beserta perubahan-perubahannya.