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ASSESSMENT OF COMMUNITY PHARMACISTS' KNOWLEDGE AND LEGAL PERCEPTION OF GENERIC DRUGS RETAIL PHARMACIES IN CAN THO CITY IN 2023-2024

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ABSTRACT

Background: *As generic drugs play an increasingly vital role in the pharmaceutical ecosystem, assessing community pharmacists' knowledge of these medications and their perception of the legal policies governing them is crucial. This assessment is essential for enhancing pharmacists' ability to effectively distribute these drugs to consumers.* ***Objectives:*** *To evaluate community pharmacists' knowledge of generic drugs, and their perception of the legal policies related to these medications in retail pharmacies in Can Tho City.* ***Materials and methods:*** *A descriptive cross-sectional study employed self-administered questionnaires and direct interviews with 188 community pharmacists across nine districts of Can Tho City.* ***Results:*** *Among the 188 community pharmacists, 115 (61.1%) demonstrated a good level of knowledge regarding generic drugs. Their perception of the legal policies related to these medicines was also rated as good, with a median score of 4 across all five assessment categories.* ***Conclusions:*** *This study provides important insights into pharmacists' knowledge of generic drugs. The findings can inform the development of strategies to improve community pharmacists' knowledge, thereby strengthening and promoting the role of generic drugs in the Vietnamese pharmaceutical market, particularly in Can Tho City.*

Keywords: *generic, knowledge, legal policies, community pharmacists, Can Tho.*

I. INTRODUCTION

In recent years, to address the financial burden of healthcare, many countries have promoted the use of generic drug as an essential component of their healthcare systems. This promotion has been achieved through various policies, initiatives, and strategies. For example, the implementation of generic drug utilization in Sweden began in October 2002 [1]. In Europe, generic drug account for 67% of prescriptions, and their use is estimated to reduce overall healthcare costs by 100 billion euros annually [2]. A survey has shown that retailers' perceptions are influenced by their knowledge and the sources of that knowledge. The study results indicate that community pharmacists primarily acquire their knowledge of generic drugs from universities and colleges (62.8%) [3]. This result is lower than that of a study conducted in Lebanon (74%) [4]. However, in Vietnam, there is a gap in research specifically investigating pharmacists' knowledge of generic drugs and their perception of the related legal policies. Can Tho City, a major urban center in the Mekong Delta region with a large population and a diverse, expanding network of pharmacies, is an ideal location for this study. Recognizing this gap, our research team conducted the study titled

"Assessment of Community Pharmacists' Knowledge and Legal Perception of Generic Drugs in Retail Pharmacies, Can Tho City, 2023-2024."

II. MATERIALS AND METHODS

2.1. Materials

Pharmacists working in GPP-certified (Good Pharmacy Practice) retail pharmacies and drugstores in Can Tho City during 2023-2024 will be included in the study. Inclusion Criteria include pharmacists who meet the specified criteria and voluntarily agree to participate in the study. Exclusion Criteria include those who do not respond to the survey questions due to internal regulations, provide incomplete or inaccurate answers due to time constraints, and those working in pharmacies that have ceased operations.

2.2. Methods

- Study design: This study will employ a descriptive cross-sectional design.

- Sample size:

$$n = \frac{Z^2_{(1-\frac{\alpha}{2})} \cdot p(1-p)}{d^2}$$

The sample size for a large population is calculated using the following parameters: n: sample size for the study, Z: value from the standard distribution ($Z_{0.95}$ = 1.96 for a 95% confidence interval), α: level of statistical significance (α=0.05), d: margin of error between the sample estimate and the population parameter (d=0.06), p: estimated proportion in the population. Based on Ninh The Vu's 2019 survey in Vietnam, which reported that 80% of pharmacists have a positive attitude toward using generic drugs [5], p is set to 0.8. Substituting these values into the formula yields a minimum sample size of 170. To account for potential pharmacy closures or temporary halts in operation during the study, the sample size is increased by 11%, bringing the total to 188.

- Sampling method: Based on the list of pharmacies and drugstores provided by the Can Tho Department of Health (2022), we compiled the quantity and calculated the percentage of pharmacies and drugstores, and the number of samples to be taken from each district in Can Tho City. With a study sample size of 188, proportional sampling will be applied: 64.65% of 188 (122 samples) will be taken from pharmacies in the districts, and 35.35% (66 samples) from drugstores in the rural areas of Can Tho City, the specific sample sizes have been determined as follows: pharmacies: Ninh Kieu (62), Cai Rang (17), O Mon (12), Thot Not (9), Binh Thuy (22) and drugstores: Vinh Thanh (11), Thoi Lai (18), Phong Dien (19), Co Do (18).

- Study contents: The study investigates general information such as gender, age, professional qualification, experience, type of pharmacy and area about the research subjects while also assessing the knowledge and legal policies related to generic drugs among community pharmacists [5]. An assessment of community pharmacists' knowledge of generic medications and their perception of relevant legal policies was conducted through a survey. The survey consists of an eight-question interview, with each question offering three options (true, false, or unknown). In this survey, respondents receive 1 point for a correct answer and 0 points for a wrong answer or if they do not know the answer, resulting in a total score ranging from 0 to 8. The scores are categorized into three levels: Poor knowledge: score below 50% of the total score (below 4 points); Average knowledge: score

ranging from 50% to 70% of the total score (4 to 5 points); Good knowledge: score above 70% of the total score (6 points or higher) [6]. The survey also evaluates community pharmacists' perceptions of legal policies related to generic drugs using a 5-point Likert scale, ranging from "very negative" to "very positive".

- **Statistical analysis:** After data collection, the questionnaires were checked, cleaned, and entered Excel 2003, then analyzed using SPSS 20.0.

- **Ethics approval:** The research proposal has been approved by the Ethics Committee No. 23.150.SV/PCT-HĐĐĐ on December 25, 2023, for biomedical research at Can Tho University of Medicine and Pharmacy.

III. RESULTS

3.1. General information about the subjects of study

Table 1. General information on the study subjects.

Characteristic		Frequency (n)	Percentage (%)
Gender	Male	63	33.5
	Female	125	66.5
Age (years)	From 20 to 29	98	52.1
	From 30 to 39	52	27.7
	From 40 to 49	21	11.2
	From 50 to 59	10	5.3
	From 60 and above	7	3.7
Professional qualification*	Pharmacy Intermediate	41	21.8
	College of Pharmacy	60	31.9
	University of Pharmacy	87	46.3
Experience (years)	From 0 to 1	33	17.6
	From 1 to 3	62	33
	From 3 to 5	31	16.5
	From 5 to 10	36	19.1
	From 10 and above	26	13.8
Type of pharmacy	Private pharmacy	135	71.8
	Chain pharmacy	53	28.2
Area	Urban areas	107	56.9
	Rural areas	81	43.1

**University Pharmacists: undergo five years of training. College Pharmacists: complete three years of training. Intermediate Pharmacists: receive two years of training.*

Most of the pharmacists are women (66.5%), while men make up 33.5%. Over half of the pharmacists are between 20 and 29 years old (52.1%). A significant proportion hold a university degree in pharmacy (46.3%). Most have 1 to 3 years of experience (33.0%), and work in private pharmacies (71.8%) and are based in urban areas (56.9%).

3.2. General knowledge of community pharmacists about generic drugs

Table 2. Evaluation of community pharmacists' knowledge on generic drugs

Contents	True n (%)	False n (%)	Unknown n (%)
K1. Generic drugs are typically manufactured without a license from the original innovator company but are marketed after the expiration of patents or other exclusive rights (True)	155 82.4%	25 13.3%	8 4.3%

Contents	True n (%)	False n (%)	Unknown n (%)
K2. The name of a generic drug must be different from the name of the main active ingredient. (False)	119 63.3%	50 26.6%	19 10.1%
K3. Generic drugs are not subject to patent protection but are protected by trademarks and industrial designs. (True)	156 83%	21 11.2%	11 5.8%
K4. In Vietnam, generic drugs must undergo rigorous clinical trials and bioequivalence studies before being approved for market. (False)	154 81.9%	26 13.8%	8 4.3%
K5. In Vietnam, generic drugs only need to demonstrate pharmaceutical equivalence to the original drug, which means they must have the same active ingredient, dosage form, route of administration, and meet the same quality standards to be registered. (False)	77 41%	78 41.5%	33 17.5%
K6. Before approving a generic drug, the FDA requires rigorous testing to ensure it can be substituted for the brand-name drug, a process known as 'generic equivalence'. (True)	158 84%	22 11.7%	8 4.3%
K7. A drug is considered a 'generic equivalent' when it has the same therapeutic effect as the original brand-name medicine, so all generic equivalents are therapeutically equivalent. (False)	159 84.6%	24 12.8%	5 2.6%
K8. Generic drugs are considered as safe and effective as brand-name drugs when they are bioequivalent and meet the same quality standards (True)	160 85.1%	22 11.7%	6 3.2%

**The part in parentheses (true/false) is the correct answer.*

Most community pharmacists correctly answered questions on "bioequivalence" (85.1%) and "generic equivalence" (84.6%). However, 41.5% answered incorrectly and 17.5% were unsure about "generic drug registration regulations in Vietnam."

Figure 1 shows the distribution of pharmacists' overall knowledge scores on generic drugs.

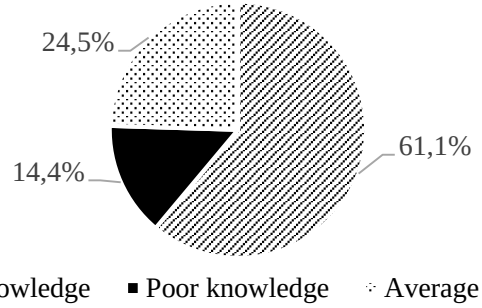

Figure 1. Categorization of pharmacists' knowledge levels regarding generic drugs.

The knowledge levels of pharmacists were distributed as follows: 61.1% had a high level of knowledge, 24.5% (n=46) had an average level, and 14.4% had a low level.

3.3. Community pharmacists' awareness of legal policies regarding generic drugs

Table 3. Assessment of pharmacists' awareness on legal policies for generic drug.

Contents	1 n (%)	2 n (%)	3 n (%)	4 n (%)	5 n (%)
LP1. The government has issued numerous policies to streamline the application process for registering the circulation of generic drugs.	9 4.8%	11 5.9%	32 17%	100 53.2%	36 19.1%

Contents	1 n (%)	2 n (%)	3 n (%)	4 n (%)	5 n (%)
LP2. For drug procurements funded by the state budget, health insurance, and the legal revenues of public healthcare institutions, domestically produced generic drugs and biosimilars with valid Vietnamese marketing authorizations should be prioritized.	10 5.3%	10 5.3%	30 16%	103 54.8%	35 18.6%
LP3. In Vietnam, generic drugs are exempt from clinical trials prior to market authorization.	9 4.8%	9 4.8%	34 18.1%	79 42%	57 30.3%
LP4. Eliminating barriers related to the interests, misconceptions, and lack of information about generic drugs among healthcare professionals and patients can be achieved by developing a complementary and synchronized legal framework.	5 2.7%	5 2.7%	28 14.9%	74 39.3%	76 40.4%
LP5. The pharmacist in charge may substitute a prescribed drug with another drug having the same active ingredient, dosage form, and dosage, provided that the patient consents to the substitution. The pharmacist must assume responsibility for this substitution.	10 5.3%	8 4.3%	29 15.4%	99 52.7%	42 22.3%

**The rating scale was as follows: 1 for Very Negative, 2 for Negative, 3 for Neutral, 4 for Positive, and 5 for Very Positive.*

Most pharmacists agree that the government should prioritize funding for generic drugs and simplify their registration process, with a good perception of generic drug substitution.

3.4. Cronbach's Alpha reliability analysis

Table 4. Cronbach's Alpha Coefficient Table for Knowledge and Legal Policy

Manifest variable	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correctlation	Cronbach's Alpha if Item Deleted
Knowledge: Cronbach's alpha = 0.834				
K1	17.94	12.049	0.731	0.794
K2	18.26	13.851	0.22	0.867
K3	17.91	12.072	0.781	0.789
K4	17.95	12.168	0.689	0.799
K5	18.63	14.576	0.093	0.886
K6	17.9	12.001	0.79	0.788
K7	17.91	11.869	0.797	0.786
K8	17.89	12.063	0.78	0.789
Legal policy: Cronbach's alpha = 0.872				
LP1	15.59	10.778	0.712	0.842
LP2	15.59	10.639	0.733	0.837
LP3	15.47	10.593	0.686	0.849
LP4	15.23	10.905	0.735	0.837
LP5	15.53	11.138	0.633	0.861

The Cronbach's alpha showed that variables K2 and K5 had item-total correlations below 0.3, so they were removed. After removal, reliability met the criteria, with all items having reliability above 0.6 and item-total correlations over 0.3.

IV. DISCUSSION

4.1. Knowledge of community pharmacists about generic drugs

Among the 188 community pharmacists who participated in the survey, 115 scored between 6 and 8 points, accounting for 61.1% of the total. Within this group, 49 answered all 8 knowledge questions correctly, including 26 pharmacists with university degrees, 18 with college degrees, and 5 with intermediate qualifications. The knowledge scores of community pharmacists followed a non-normal distribution, with a median of 6.0 (interquartile range: 25%-75%, from 5.0 to 8.0 points), and a mean of 5.6 out of 8, which is equivalent to 7 out of 10. To facilitate comparisons with other international studies, the mean value was used. The knowledge score of community pharmacists in Can Tho (Mean ± SD: 7 ± 2.2) was higher than that reported by Shraim *et al.* in Palestine (Mean ± SD: 5.91 ± 1.27) and Awaisu *et al.* in Qatar (Mean ± SD: 6.8 ± 1.6) [7, 8]. After verifying the reliability of the scale using Cronbach's Alpha, the research team eliminated two questions that were considered inappropriate due to a high proportion of incorrect or unknown answers. 85.1% of pharmacists correctly answered when a generic drug is considered as safe and effective as the original brand-name drug. Questions K6 and K7 on "generic equivalence" were also answered correctly by most pharmacists (84% and 84.6%). Almost all pharmacists understood that therapeutic equivalence implies generic equivalence, but not vice versa. Additionally, 83% of pharmacists indicated that generic drugs are not subject to patents or intellectual property rights but are only protected by trade names and industrial designs. Furthermore, 82.4% showed a strong perception of the general regulation of generic drugs: "not licensed by the innovator company and marketed after the expiration of patents or other exclusive rights". This percentage is higher than the rates reported in studies by Ninh The Vu in Hanoi (35.5%), Shraim *et al.* in Palestine (59.3%), and Awaisu *et al.* in Qatar (68.3%) [5, 7, 8]. When asked about generic drug trials, 81.9% of pharmacists provided correct answers. According to Vietnamese drug registration requirements, generic drugs are not required to undergo animal studies, clinical trials, or bioavailability assessments. Instead, they only need to undergo bioequivalence testing with the original brand-name drug if the active ingredient is listed among the substances requiring bioequivalence data for drug registration [9]. Some community pharmacists may have answered incorrectly due to training programs not highlighting the differences between trial types, causing confusion about clinical trials and bioequivalence studies [10].

4.2. Community pharmacists' perception of legal policies regarding generic drugs

Most pharmacists acknowledged the government’s efforts to simplify drug registration and promote generic drug use, especially in public healthcare. [11]. Regarding drug substitution rights, the study results indicate that pharmacists have a solid perception of the legal regulations related to drug substitution, including who is authorized to substitute drugs, the conditions for substitution, and the associated legal liabilities, as specifically outlined in Circular 02/2018/TT-BYT [12]. However, a more comprehensive legal framework is still needed not only to enhance knowledge but also to regulate actual practices, prevent regulatory violations, address conflicts of interest, and strengthen pharmacists' accountability.

V. CONCLUSION

Overall, community pharmacists in Can Tho City showed good knowledge, though some had misconceptions or unclear understanding of regulations on generic drugs. A limitation of this study is the lack of analysis on the relationship between demographics and knowledge levels. Future studies should explore this to clarify findings and offer solutions to improve education and pharmacy practice in Can Tho.

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