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KNOWLEDGE AND COMPLIANCE WITH DRUG LEGISLATION IN THE COMMUNITY PHARMACY OF DHARAN

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ABSTRACT

Background: Pharmacists are crucial in the healthcare system due to their accessibility, and to provide quality care, they must be knowledgeable about legislation and fully comply with it.

Objective: This study aimed to evaluate knowledge and compliance with drug legislation by Community Pharmacies (CPs).

Method: A cross-sectional survey was conducted on Dharan's CPs, assessing their knowledge and compliance status through observation and structured questions using both descriptive and analytic statistics.

Results: Most community pharmacists (58.1%) are unaware of the penalties for non-compliance, though they possess good knowledge about drug categorization and narcotic record-keeping (95.2%). While 94.11% of pharmacists use lock-and-key systems for narcotics, only 31% keep records of their sales and distribution. Additionally, 70.5% display their firm registration certificate, 68.6% have up-to-date registration, and 77% are operated by qualified personnel. However, many fail to provide necessary facilities, such as wheelchair accessibility (22.9%) and counselling rooms (34.3%), and only 18.1% have shelves covered by glass. In prescription handling, most pharmacists do not check for prescriber signatures (70.5%) or prescription dates (69.5%). There is a weak positive correlation between knowledge and compliance ($r=0.277$) and between knowledge and working experience ($r=0.2$), with both correlations being statistically significant ($P<0.05$).

Conclusion: National regulatory bodies should organize educational programs for community pharmacists in Dharan to improve their role in promoting rational drug use.

KEYWORDS: Legislation, Compliance, regulatory, legal requirements, Pharmacy

IMPACTS ON PRACTICE

- The study reveals significant legislative knowledge and compliance gaps among community pharmacists, highlighting the need for national regulatory bodies to organize targeted educational programs to improve understanding and adherence to regulations.
- Many community pharmacies lack essential facilities, such as wheelchair accessibility and counselling rooms, indicating a need for infrastructure enhancements to ensure comprehensive patient care and compliance with standards.

INTRODUCTION

Pharmacists serve as the primary point of contact within the healthcare system due to their widespread accessibility, especially in many developing countries.[1] However, the inappropriate distribution and uncontrolled dispensing of medications through community pharmacies remain significant issues in these regions.[2] These dispensing practices can be examined through the lens of structure, process, and outcome. The structure comprises two critical components: the pharmacy premises, which must comply with legal standards and possess the necessary materials and facilities for proper drug storage and dispensing, and the dispenser, a qualified individual with the appropriate knowledge, qualifications, and skills.[3]

In Nepal, the government has established the Department of Drug Administration (DDA) as a national regulatory authority to realize the goal of "Universal Health Coverage." The DDA is responsible for ensuring that all medicinal products meet acceptable standards of quality, safety, and efficacy and that all practices related to the manufacture, storage, and distribution of these products adhere to these standards until they reach the end user.[4] Key regulations, including the Drug Act of 1978 and the Drug Sales and Distribution Codes of 1984, provide the legal framework for the availability and rational use of safe, effective, and high-quality drugs. Compliance with these laws is essential for efficient pharmacy practice.

The Drug Act of 1978 includes provisions for the manufacture, sale, distribution, export, and import of drugs, mandating that all individuals and firms involved in these activities register with the DDA and obtain the necessary certifications. For instance, Chapter 4, Section 10 of the Drug Act requires the registration of individuals and firms, and Chapter 4, Section 11 outlines the renewal process of the registration certificate.[5] Additionally, penalties for non-compliance are detailed in Chapter 7, Section 34, which stipulates imprisonment or fines for unregistered sales and distribution of drugs.[5] The classification of drugs into categories A, B, and C, based on the authority of distribution, further ensures that specific drugs are only dispensed by qualified personnel.[5]

The International Pharmaceutical Federation (FIP) and the World Health Organization (WHO) have set global standards for Good Pharmacy Practice (GPP), emphasizing the importance of quality in pharmacy services. These guidelines aim to enhance pharmaceutical care by improving clinical and economic outcomes in patient health care.[6, 7] In collaboration with WHO, the Nepal Pharmacy Council has developed National Good Pharmacy Guidelines to improve pharmaceutical care. These guidelines address facilities, manpower requirements, documentation systems, and prescription handling, emphasizing the need for a clean and accessible environment, proper storage and documentation of drugs, and the maintenance of statutory and operational records.[8]

Despite the existence of these comprehensive regulations and guidelines, their implementation has been inconsistent, hindering the proper development of the pharmacy profession in Nepal. Challenges include a shortage of qualified pharmacists, the operation of pharmacies by individuals with limited knowledge of drug legislation, and a lack of standard practice guidelines and enforcement mechanisms.[2, 9, 10] These barriers highlight the urgent need for effective enforcement and regular inspections to ensure compliance with established standards.

Few studies have evaluated pharmacy outlets' compliance with regulatory provisions in Nepal. This study aims to assess the compliance of community pharmacies in Dharan with Good Pharmacy Practices, identify deficiencies, and promote drug safety, efficacy, and rational use. Additionally, it evaluates community pharmacists' knowledge of drug legislation and explores the correlation between knowledge and compliance. With many pharmacy outlets operated by non-pharmacists driven by profit motives and lacking legislative knowledge, this study is crucial. No prior studies have assessed this in Dharan.

The primary goal is to evaluate both the knowledge of drug legislation and compliance among community pharmacists in Dharan. Findings may inform regulatory authorities for periodic inspections, effective implementation, and corrective actions to address deficiencies. This research aims to enhance pharmaceutical care quality and ensure rational drug use in Nepal, ultimately improving healthcare outcomes in the region.

METHODS

Ethics approval

Approval was obtained from the Department of Drug Administration (Ref no:329) before data collection. A written informed consent was obtained before participation in the study.

Study design

A cross-sectional survey was conducted in Dharan, Nepal, targeting operating Pharmacies. The study was conducted during a two-week period between January 2018 and February 2018.

Study population sample size and sampling method

The study targeted all operating Pharmacies in Dharan, Nepal. From DDA, it was known that about 198 pharmacies in Dharan were registered with DDA. A pilot study from 16 CPs reveals that 94% of the pharmacists have good knowledge and adequate compliance with legislation set by national regulatory bodies, and a total of 105 pharmacies would provide a representative sample size with a 3% margin of error and a 95% confidence level. Stratified sampling was done based on the pharmacy ward number.

Questionnaire design and Validation

The questionnaire consists of 3 main parts. The transcript for the study was written in English and later translated into Nepali without changing the meaning. 1st part consists of demographic information, which includes 12 questions (name of the pharmacy, PAN number, DDA registration number, age of participant, sex, educational level, country of graduation, location of pharmacy, presence of vaccine, presence of narcotics, arrangement of drugs and working experience. The second part consists of knowledge questions containing 9 questions constructed from the Drug Act 2035 [5] and a portion of the Drug Sales and Distribution Code 2041.[11] The third part consists of compliance questions containing 23 questions constructed from Good Pharmacy Practice.[8]

A structured questionnaire for knowledge was constructed from the Drug Act 2035 by consulting with legislation experts, and instrument validity was checked by conducting a pilot study on 16 Community pharmacies (CPs) and finding their reliability using Cronbach alpha, 0.706. The compliance questions used in the tool had been established based on similar previously published studies.[12, 13]

Procedure

Demographic and knowledge responses were obtained from participants through interviews, while compliance information was gathered through the observation of relevant documents, premises, and additional participant interviews.

Each correct response to the knowledge questions was scored as one point, while incorrect responses received a score of zero. Similarly, for compliance, one point was awarded, and zero points for non-compliance. The total knowledge and compliance scores for each participant were then calculated for analysis.

Data analysis

The data was entered into the SPSS version 25 for Windows (SPSS) for analysis. Both descriptive and analytic statistics were utilized. For descriptive analysis, results were expressed as numbers, percentages, and mean (±SD and 95% CI). The Mann- Whitney U test, the Kruskal-Wallis test, and the Chi-square test were used based on the nature of the data to assess intergroup differences. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Out of 109 samples, responses were obtained from 105 CPs, yielding a response rate of 96.33%. The average working experience of participants was 4.11±4.21 years. Regarding the DDA registration number, 70.48% of CPs showed their DDA registration number, while 29.52% failed to do so. Additionally, 71.4% of CPs provided vaccination services, whereas 28.6% did not. Only 29.5% of CPs kept narcotics. In terms of drug arrangement practices, more CPs arranged drugs therapeutically compared to those who arranged them alphabetically (21%) or randomly (3.8%).

The educational background of the drug dispensers revealed that 49.52% had a diploma in pharmacy, and an equal percentage came from other educational backgrounds. Only one dispenser held a Bachelor's degree in pharmacy, and no dispensers had a Master's degree in pharmacy. Detailed information is presented in Table 1.

Table 1 Detail socio-demographic characteristics and variables information

Variables	Category	Frequency	Percentage (%)
Gender	Male	78	74.3
	Female	27	25.7
Educational level of participant	Diploma in pharmacy	51	49.5
	Bachelor in Pharmacy	1	1
	Others	52	49.5
Shown DDA registration number	Yes	74	70.5
	No	31	29.5
Pharmacy location	Near Hospital	62	59
	Far Hospital	43	41
Arrangement of drugs	Alphabetically	22	21
	Therapeutically	79	75.2
	Randomly	4	3.8
Presence of Vaccines	Yes	75	71.4
	No	30	28.6
Presence of Narcotics	Yes	31	29.5
	No	74	70.5

Most of the community pharmacists are not aware of the penalty; similarly, they have poor knowledge about the validity of the registration certificate from the date of issue by DDA, the dispensing of over-the-counter (OTC) drugs, and the time duration for which the copy of the prescription of the dispensed narcotics should be kept safely.

From Table 2 it is concluded that community pharmacists have good knowledge about Group A and B drugs and also about the records that must be maintained during the dispensing of narcotics.

Table 2 Response of CPs towards knowledge questions

Question Number	Correct Answer		Incorrect Answer	
	Frequency	Percentage	Frequency	Percentage
1	39	37.1	66	62.9
2	75	71.4	30	28.6
3	61	58.1	44	41.9
4	100	95.2	5	4.8
5	101	96.2	4	3.8
6	40	38.1	65	61.9
7	32	30.5	73	69.5
8	100	95.2	5	4.8
9	44	41.9	61	58.1

Table 3 below shows that 94.11% (n=32) of CPs keep Narcotics separately with the LOCK and KEY system, and 31%(n=33) keep a record of the narcotics during their sales and distribution. 70.5% of CPs displayed the firm registration certificate, 68.6% of CPs have their registration certificate up to date, and 77% of CPs are operated by qualified personnel. Most of the CPs fail to provide the facilities in terms of accessibility to the wheelchair patient, counselling room, etc. Only 22.9% of the CPs are accessible for wheelchair patients, and only 34.3% of CPs have counselling rooms. Only 18.1% of the CPs have the shelves covered by glasses. From this data, we can conclude that the quality of the drug is at risk because it may be deteriorated by dust, dirt, rodents, etc. 71.4% of CPs provide vaccination facilities, 26.7% of CPs have an alternative source of energy for refrigerators and 66.7% of CPs don't keep non-drug item in refrigerator.95.2% of CPs keep the expired drugs in separate shelves. In the case of prescription handling, most of the CPs are not aware of the prescriber signature to be checked (only 21.5% check the signature) and the prescription date to be checked (only 30.5% of CPs check the date of a prescription).

Table 3 Observation on compliance (N=105)

Variables	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Registration Certificate Displayed	74	70.5	31	29.5
Qualified personnel present	81	77.1	24	22.9
Registration certificate Validity	72	68.6	33	31.4
Signboard Present	78	74.3	27	25.7
Cleanliness	99	94.3	6	5.7
Accessibility to wheelchair patients	24	22.9	81	77.1
Counselling Room	36	34.3	69	65.7
Glass covering present	19	18.1	86	81.9

Dosage forms separation	102	97.1	3	2.9
Refrigerator Present	75	71.4	30	28.6
Alternative source for refrigerator	28	26.7	77	73.3
Non-Drug item absent in refrigerator	70	66.7	35	33.3
Expiry drug separation	100	95.2	5	4.8
Lock and Key for Narcotic	32	94.1	73	5.8
Record for Narcotic and Psychotropic	33	31.4	72	68.6
Purchase Record	104	99.0	1	1.0
Expired drug record	43	41.0	62	59.0
Inspection Book Present	31	29.5	74	70.5
Prescriber signature checked	31	21.5	74	70.5
Prescription Date checked	32	30.5	73	69.5
Patient name checked	92	87.6	13	12.4
Total quantity of drugs checked	104	99.0	1	1.0
Duration of Treatment checked	105	100	0	0.0

Table 4 below shows the mean knowledge total score and compliance scores by various categories of variables. The Kruskal-Walli's test reveals a significant difference in knowledge about drug legislation based on educational level ($H(2) = 14.159$, $p = 0.001$), indicating that higher education levels are associated with greater knowledge. In contrast, the Mann-Whitney U test shows no significant difference in knowledge according to gender ($U = 1016$, $p = 0.782$). Additionally, there is no significant difference in knowledge based on the location of the pharmacy ($p = 0.207$). Regarding compliance, the p-value is less than 0.05, leading to the rejection of the null hypothesis and highlighting a significant difference in compliance based on the qualifications of personnel.

Table 4 Mean score and associations with various variables.

Variables	Category	Mean Score	P-value
	Association with knowledge score		
Gender	Male	5.63	0.782^{U}
	Female	5.67	
Education Level	Diploma in Pharmacy	6.21	0.001^{H*}
	Bachelor in Pharmacy	4	
	Others	5.10	
Pharmacy Location	Near Hospital	5.79	0.207^{X2}
	Far from Hospital	5.42	
	Association with compliance score		
Qualified person	Present	16.46	0.000^{X2*}
	Absent	15.17	

[H] Kruskal-Wallis.

[U] Mann-Whitney U test.

[X2] Chi square test

**** Shows significant at p-value < 0.05.***

The correlation analysis reveals significant relationships between knowledge, compliance, and working experience. Firstly, the Pearson correlation coefficient (r = 0.277) indicates a weak positive correlation between knowledge and compliance. The p-value of 0.004, signifies that there is a significant correlation between knowledge and compliance. Secondly, the Pearson correlation coefficient (r = 0.200) shows a weak positive correlation between working experience and knowledge of legislation. The p-value of 0.04, indicates a significant correlation between working experience and knowledge of legislation.

DISCUSSION

The primary finding of this study indicates that pharmacists in Dharan possess an average level of knowledge regarding drug legislation, and the compliance of community pharmacies with legal requirements is generally good, though none fully adhere to all legal mandates. This mirrors findings in other regions, suggesting a widespread issue of partial compliance in community pharmacies.

The study reveals that only a small proportion (30.5%) of CPs in Dharan are aware of the penalties for selling and distributing drugs without firm registration. This limited awareness is concerning and indicates a need for enhanced education and enforcement. Similar studies have reported varying levels of awareness regarding legal penalties.[14] This inconsistency in knowledge may be due to inadequate enforcement and dissemination of legislative information in practice.

On a more positive note, pharmacists in Dharan demonstrated high knowledge in specific areas, such as the categorization of drugs based on dispensing authority. The study found that 96.2% of pharmacists correctly identified the requirements for dispensing antibiotics and 95.2% for dispensing Fentanyl. This high level of knowledge is likely due to the availability of this information on drug leaflets and its regular practice. However, opinions on the dispensing of over-the-counter (OTC) drugs varied widely among pharmacists, reflecting a lack of definitive information. This variability in knowledge is consistent with findings in other regions, indicating a common issue that needs to be addressed through better training and dissemination of information.[4, 7, 12, 15]

The compliance of community pharmacies in Dharan with legal requirements is generally good, but there are significant gaps. The study found that around 22.9% of the pharmacies were operated by untrained personnel. This may be due to the practice of certificate holders (i.e., pharmacists) not working in the pharmacy regularly,

but only during certain days of the week for brief periods.[16] This practice undermines the quality of pharmacy services and adherence to legal standards.

Approximately 30% of CPs failed to display their registration certificates during the survey, and 31.4% had not renewed their certificates. These findings are similar to those reported by Hussain in Pakistan, where half of the pharmacies did not display certificates, and two-thirds had expired or unavailable certificates.[12] This similarity suggests that weak enforcement of drug legislation and profit-driven motives are common issues in both countries.

When assessing the facilities of pharmacies, three key indicators were found to be inadequate. Only 22.9% of CPs were accessible to wheelchair patients, 34.3% provided a separate counselling room, and 28.6% failed to offer vaccination facilities. These results are comparable to those obtained by Wijesinghe in Sri Lanka, indicating that similar facility-related challenges exist across different regions.[16] The lack of accessibility and specialized facilities highlights the need for significant improvements in the infrastructure of community pharmacies to meet diverse patient needs.

Furthermore, only 18.1% of CPs had glass coverings for shelves, and 44.8% lacked an alternative source of electricity for cold chain maintenance. The poor state of drug storage facilities poses a significant risk of drug deterioration, which can compromise the efficacy and safety of medications.[14] This issue is not unique to Dharan, as similar challenges have been reported in other studies, suggesting a need for global improvements in pharmacy infrastructure.

A significant association was found between the education level of pharmacists and their knowledge of drug legislation. However, no statistically significant association was observed between education level and compliance. This finding suggests that while education improves knowledge, it does not necessarily translate into better compliance. This could be due to various factors, including a lack of resources or motivation to implement knowledge effectively.

The study revealed a weak positive correlation between knowledge and compliance ($r=0.277$, $P<0.05$), indicating that while knowledge contributes to compliance, other factors also play a significant role. This finding aligns with other studies that have reported similar correlations, suggesting that knowledge alone is not sufficient to ensure compliance.

Additionally, there was a weak positive correlation between knowledge and working experience ($r=0.2$, $P<0.05$), suggesting that experience slightly enhances knowledge but does not necessarily lead to better compliance. This underscores the importance of continuous professional development and practical training to ensure that pharmacists can apply their knowledge effectively in their practice.

Comparing our findings with other research reveals several common themes and differences. For instance, the issue of untrained personnel operating pharmacies has been reported in other studies, such as those conducted in Pakistan and Sri Lanka.[12, 16] This highlights a widespread problem that needs to be addressed through stricter enforcement of regulations and better training programs.

The similarity in facility-related challenges, such as lack of accessibility and inadequate storage conditions, further underscores the need for global improvements in pharmacy infrastructure.[13, 16] These issues are not unique to Dharan and suggest that pharmacies worldwide face similar challenges that impact the quality of care they provide.

LIMITATIONS

This study is limited to Dharan City, so the findings may not represent CPs in other regions of Nepal. The data collection period was specific, capturing only the present situation. Some dispensers refused to participate, and some pharmacies were closed, leading to potential sampling bias. The use of a self-administered questionnaire could introduce desirability bias and misidentification as DDA officers caused some CPs to fearfully provide data, possibly affecting accuracy. A national study is recommended for confirmation.

CONCLUSION

While community pharmacists in Dharan have a reasonable level of knowledge about drug legislation and comply with certain legal requirements, there is still a need for improvement. The findings highlight the importance of better enforcement of drug laws, continuous education, and resource provision to enhance compliance. By addressing these issues, we can ensure that community pharmacies provide safe, effective, and patient-centered services. Future research should focus on identifying and addressing the barriers to full compliance to ensure the safe and effective operation of community pharmacies.

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Questionnaire in English

Questionnaires on knowledge of legislation to community pharmacists

1. As per the provision of drug act, how long shop or frim registration certificate will valid from the date of issue by DDA?
   a) One year b) Two year
   c) Three years d) I don't know
2. After the expiry of validity period of firm registration certificate when it must be renewed?
   a) annually within 35 days of expiry b) after two years within 35 days of expiry
   c) annually within 2 months of expiry d) I don't know
3. After the expiry of validity period, within how much time we can apply for renewal by giving specific reason?
   a) 6 months b) 12 months
   c) 3 months d) I don't know
4. Dispensing of Fentanyl can be done?
   a) With prescription in presence of pharmacist b) Without prescription in presence of pharmacist
   C) On the basis of personal experience d) I don't know
5. Dispensing of antibiotics can be done?
   a) On the basis of personal experience b) With prescription in presence of pharmacist
   c) Without prescription in presence of pharmacist d) I don't know
6. Dispensing of OTC drugs can be done?
   a) On the basis of personal experience b) Only with prescription in presence of pharmacist
   c)Only without prescription in presence of pharmacist d) I don't know
7. What will be the penalty as per provision of drug act, if any firm sells the drugs without the firm registration certificate?
   a) Imprisonment not exceeding 3 years or fine not exceeding 25000 or both
   b) Imprisonment not exceeding 1 years or fine not exceeding 5000 or both
   c) Life imprisonment
   d) I don't know
8. As per the provision of drug act, how narcotic drugs can be kept safely?
   a) In a separate place without lock and key system
   b) In a separate place with lock and key system
   c) With other drugs
   d) I don't know
9. As per the provision of drug act, how the records of narcotic and poisonous drugs can be maintained?
   a) Record is not mandatory
   b) Maintain record in a prescribed format and prescription attachment is not mandatory
   c) Maintain record in a prescribed format and prescription attachment is mandatory
   d) I don't know

Questionnaires on Compliance of drug legislation by community pharmacy

1. Pharmacy registration certificate displayed:	a) Yes	b) No
2. Presence of qualified personal:	a) Yes	b) No
3. Validity of registration certificate:	a) Yes	b) No
4. Presence of signboard:	a) Yes	b) No
5. Cleanliness maintained at interior and exterior of pharmacy:	a) Yes	b) No
6. Conveniently accessibility to people using wheelchair:	a) Yes	b) No
7. Counselling for confidentiality:	a) Yes	b) No
8. Glass covering on drug storage shelves:	a) Yes	b) No
9. Solid and liquid dosages form separated:	a) Yes	b) No
10. Presence of Refrigerator to maintain cold chain:	a) Yes	b) No
11. Alternative source of electricity:	a) Yes	b) No
12. Presence of non-drug items in refrigerator:	a) Yes	b) No
13. Separate shelves for expired drugs:	a) Yes	b) No
14. Separate shelves for narcotics:	a) Yes	b) No
15. Record of narcotics and Psychotropic:	a) Kept	b) Not Kept
16. Availability of warranties and Purchased record:	a) Yes	b) No
17. Availability of expired drug record:	a) Yes	b) No
18. Availability of inspection book:	a) Yes	b) No
19. Prescription requirements:		
a) Signature of prescriber checked:	i) Yes	ii) No
b) Date of prescription checked:	i) Yes	ii) No
c) Name of Patient checked:	i) Yes	ii) No
d) Total quantity of drug checked:	i) Yes	ii) No
e) Dosage/Duration of treatment checked:	i) Yes	ii) No