ORIGINAL ARTICLE

Exploring community pharmacists' and drug retailers' knowledge and perception regarding generic medicine in Dharan, Nepal

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ABSTRACT

Introduction: The use of generic medicine still remains very low in Nepal as compared to other developed nations. Knowledge and perception of generic medicines among community pharmacists and drug retailers play a vital role in the promotion and use of such drugs as they are assured about their quality, safety and efficacy. The objective of the study was to assess the knowledge and perception of generic medicines among the community pharmacists in Nepal.

Methods: A cross-sectional study was conducted among community pharmacists in Dharan city from 1st January 2019 to 28th February 2019. A semi-structured questionnaire was used to collect the relevant data which consisted of sociodemographic data, questions on knowledge and perception of generic medicine having a five-point Likert scale. Descriptive statistics mean, frequency and percentage were calculated using Statistical Package for Social Science (SPSS version 25.0).

Results: Out of 77 participants, 58.4% were male and 42.9% belonged to the age group of 20-30 years. About 83% of participants agreed that generic medicines are a copy of original brand name medicines. Seventy-eight percent of participants also agreed that generic medicines are interchangeable with branded medicines. About 72% of participants believed that generic medicines produce more side effects compared to brand-name medicines. About 50% of participants did not believe that the quality of brand name medicines is required to meet higher safety standards than generic medicines. Out of 77 participants, 87% opined that they need a standard guideline for both prescriber and pharmacist on the brand substitution process.

Conclusion: The present study showed that most of the community pharmacists had adequate knowledge and positive perception about generic medicine. Pharmacists need to be continuously educated about generic medicine which ultimately leads to its promotion. The study findings would assist policymakers and stakeholders to implement and strengthen the policy regarding the promotion of generic medicines.

KEYWORDS: Community pharmacists, generic medicine, Nepal

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INTRODUCTION

According to FDA, generic medicine is identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.[1] Such medicine are cheaper and hence their use is being promoted globally to reduce the costs of therapy and to increase access to healthcare.[2] The presence of more generic medicines in the pharmaceutical market also makes the market competitive, which ultimately plays an important role in lowering the prices of other medicines including generic equivalents.[3] Use of generic medicine still remains very low in Nepal as compared to other developed nations.

Community pharmacy is commonly termed as 'ausadhi pasal' ('medicine shop') in Nepal and community pharmacist is a person who operates it. They have a four-year undergraduate degree in pharmacy or a two-year intermediate course in pharmacy. A 'professional persons' with a few weeks to a month's basic course in medicine dispensing' also operates a community pharmacy.[4] Drug retailers are those who have received training on government-sponsored 72-h 'drug retailer orientation course' which consists of 64 lecture hours and 8 hours of hands-on training in proper storage and dispensing techniques.[5] Community pharmacists and drug retailers are the key role-players in generic substitution as they are the most likely health care professional to interact with patients regarding the use and safety of medicines. Knowledge and perception of generic drugs among community pharmacists play a vital role in the promotion and use of such drugs as they are assured about their quality, safety and efficacy.[6] They can then clarify the patients about the substitution of cheaper generic equivalents rather than choosing high-priced branded medicines which ultimately reduces the cost burden of medicines on patients.

Knowledge and perception of prescribers play a very vital role in the promotion of generic medicine. However, studies on knowledge and perception of generic drugs among community pharmacists are few in Asian countries.[7] With the advent of the mandatory requirement of the offer of generic substitution in Nepal by pharmacists, it is imperative to investigate the knowledge and perceptions of pharmacists with regards to generic medicines in order to assess if they are enabling the implementation of the policy.[8] To address this gap, this study was conducted to assess the knowledge and perception of generic medicines among the community pharmacist and drug retailers in Nepal.

MATERIALS AND METHODS

Study setting and duration: A cross-sectional study was conducted among community pharmacists in Dharan city from 1st January 2019 to 28th February 2019.

Study population: Community pharmacists and drug retailers working in Dharan city were selected for the study.

Sample size calculation: A total of 203 registered retail community pharmacies were located in Dharan during the study period according to the Department Of Drug Administration, Biratnagar, Nepal. The Raosoft sample size calculator was used to calculate a required sample size of 66 based on a population size of 203 with a 10% margin of error, 95% confidence level and 50% response distribution.[9] One hundred thirty-two community pharmacists were randomly selected.

Inclusion and exclusion criteria: The community pharmacists working in the selected pharmacies and giving consent were enrolled in the study. The pharmacists working in other pharmacies and not giving consent were excluded.

Data collection tool: A semi-structured questionnaire was prepared through extensive and relevant literature review and used to collect the relevant data.[10-12] It consisted of sociodemographic data (age, gender, educational qualification, years of experience), 9 questions on knowledge and 9 questions on perception of generic medicine on a 5-point Likert scale (Strongly Agree, Agree, Neutral, Disagree, Strongly disagree). All

of the questions were closed-ended. The questionnaire was prepared in English language and translated to Nepali by another person. It was again back-translated to English by an independent translator. The questionnaire was sent to the three subject experts to check the content validity and their suggestions were included. A pilot study was conducted on ten community pharmacists to validate the questionnaire and those data were not used in the analysis.

Ethical approval: Ethical clearance was obtained from the Nepal Health Research Council, Kathmandu, Nepal (75/2019).

Data collection methods: The community pharmacists were approached by the principal investigator. After explaining the objective of the study and taking the written consent, a face-to face interview was conducted to collect the relevant data. Personal information was not revealed to maintain the confidentiality of the participants. No incentive was given to the participants.

Statistical analysis: The data were entered into Microsoft Excel sheet 2016. Descriptive statistics mean, frequency and percentage were calculated. Data were presented in tabulated form. The statistical analysis was performed by Statistical Package for Social Science (SPSS version 25.0).

RESULTS

Out of the 132 community pharmacists selected and approached, 77 responded giving a response rate of 58.3%. Most of the participants were male (58.4%), belonged to the age group of 20-30 years (42.9%) and completed a diploma in pharmacy (58.4%). Thirty-three (42.9%) community pharmacists had attended orientation training and experience of five years or less (**Table 1**).

Table 1: Sociodemographic characteristics of the participants (n=77)

Sociodemographic characteristics	Category	Frequency	Percentage
Gender	Male	45	58.4
	Female	32	41.6
Age group in years	20 – 30	33	42.9
	31 – 40	16	20.8
	41 – 50	22	28.6
	>50	6	7.8
Educational qualification	Diploma in Pharmacy	45	58.4
	Orientation Training	21	27.3
	Bachelor of Pharmacy	3	3.9
	Others	8	10.4
Years of experience	5 or less	33	42.9
	6 to 10	17	22.1
	11 to 15	11	14.3
	16 to 20	4	5.2
	> 20	12	15.6

Knowledge of the generic medicine among the community pharmacists

About 72.7% of the participants agreed that generic medicines are a copy of original brand-name medicines (**Table 2**). Seventy-eight percent of the participants agreed that generic medicines are interchangeable with branded medicines. About 74% of participants agreed that generic medicines are therapeutically equivalent to branded medicines. Fifty-seven percent of participants agreed that generic medicine must contain the same dose as the brand name medicine (**Table 2**).

Table 2: Knowledge of generic medicine among the participants (n=77)

Knowledge of generic medicine	Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
	n	%	n	%	n	%	n	%	n	%
Generic medicines are a copy of original brand name medicines.	3	3.9	8	10.4	10	13	41	53.2	15	19.5
Generic medicines are interchangeable with branded medicines.	1	1.3	6	7.8	10	13	44	57.1	16	20.8
Generic medicines are therapeutically equivalent to branded medicines.	2	2.6	6	7.8	12	15.6	39	50.6	18	23.4
Generic medicines must be in the same dosage form (such as tablet, capsule) as branded medicines.	2	2.6	13	16.9	7	9.1	32	41.6	23	29.9
A generic medicine must contain the same dose as the brand name medicine.	2	2.6	12	15.6	19	24.7	29	37.7	15	19.5
Generic medicines produce more side effects compared to brand name medicines.	8	10.4	11	14.3	3	3.9	32	41.6	23	29.9
The quality of brand name medicines are required to meet higher safety standards than generic medicines.	21	27.3	16	20.8	3	3.9	7	9.1	30	39
Generic medicines are manufactured after the patent expiry of originator/ innovator brand.	2	2.6	9	11.7	17	22.1	22	28.6	27	35.1
Generic medicines are cheaper than original brand medicines.	1	1.3	2	2.6	4	5.2	17	22.1	53	68.8

Perception of the generic medicine among the community pharmacists

Out of 71, 87% of participants opined that they need a standard guideline for both prescriber and pharmacist on brand substitution process (**Table 3**). All participants believed that advertisements done and incentives given by the brand drugs manufacturers will influence the prescribing as well as dispensing pattern of brands rather than generic medicines (**Table 3**).

Table 3: Perception of generic medicine among the participants (n=77)

Perception of generic medicine	Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
	n	%	n	%	n	%	n	%	n	%
In my opinion we need a standard guideline for both prescriber and pharmacist on brand substitution process.	2	2.6	1	1.3	7	9.1	19	24.7	48	62.3
I believe that the use of generic medicine among patients can be increased if both prescriber and pharmacist work together.	2	2.6	4	5.2	9	11.7	27	35.1	35	45.5
I think the patients should be given enough information about the generic medicines, in order to make sure that they really understand about the medicines they take.	1	1.3	2	2.6	1	1.3	25	32.5	48	62.3
I believe that advertisements done and incentives given by the brand drugs manufacturers will influence the prescribing as well as dispensing pattern of brands rather than generic medicines.	2	2.6	3	3.9	1	1.3	19	24.7	52	67.5

Perception of generic medicine	Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
	n	%	n	%	n	%	n	%	n	%
I need more information on the issues relating to the safety and the efficacy of generic medicine in order to dispense it.	1	1.3	1	1.3	2	2.6	10	13	63	81.8
Availability of drugs will also be a factor that will affect the dispensing pattern of medicines.	2	2.6	3	3.9	1	1.3	18	23.4	53	68.8
Patients, socioeconomic factor will also affect the choice of dispensing.	4	5.2	6	7.8	3	3.9	25	32.5	39	50.6
I feel that patient's demand of medicine will influence the dispensing patterns.	15	19.5	16	20.8	7	9.1	32	41.6	7	9.1
I think Nepal Government should make the policy to encourage for the establishment of generic manufacturers.	2	2.6	4	5.2	10	13	19	24.7	42	54.5

DISCUSSION

In the present study the response rate was 58.3% and a higher response (89%) was reported in an Ethiopian study.[13] The difference might be due to the difference in the time given to complete the questionnaire and patient load to the pharmacies. More than half of the study participants were male in our study and this was similar to the report of other studies.[6,13] Majority of the participants were in the age range of 20-30 years and a similar finding was also reported by Yard.[13] However, majority of the participants (31.8%) were in the age group 31-40 years in an Indian study.[6] The majority of the participants had completed diploma in pharmacy which was similar to a report of Basak et al.[6] In contrast, the majority of participants were graduated (47.7%) in a study by Syed et al conducted in Saudi Arabia.[14] These differences might be due to the difference in guidelines for community pharmacists in different countries.

Knowledge of the generic medicine among the community pharmacists

The majority (72.7%) of the participants agreed that generic medicines are a copy of original brand name medicines. Generic medicines have exactly the same dosage, intended use, effects, adverse drug reactions, route of administration, risks, safety and strength as the original brand-name drug. Therefore, their pharmacological effects are exactly the same as those of their brand-name counterparts.[15]

More than three-fourths (78%) of the participants agreed that generic medicines are interchangeable with branded medicines. A generic drug is considered interchangeable with an innovator or a reference pharmaceutical and is effective and safe for patients in the specific indication.[16] However, narrow therapeutic index, critical dose, and highly variable medications are not freely interchangeable with their innovator counterparts, and thus demand closer laboratory and clinical monitoring than others.[17] Therefore, proper educational intervention is needed to make the community pharmacists more aware regarding interchangeable of generic and brand medicines.

About 74% of participants agreed that generic medicines are therapeutically equivalent to branded medicines and similar findings were reported in a study from New Zealand in which 70 percent of the participants had knowledge on the bioequivalence of generic medicine to the brand product.[18] This finding was higher than the studies reported from Ethiopia and Malaysia.[13,19] This difference might be the result of a difference in the educational status of the participants in these studies. Generic medicines contain as little as 80% to as much as 125% of the active ingredients as the branded medicine.[20] There is no significant difference in the extent of absorption of the brand products and their generic version when they are administered in the same molar dose under similar experimental conditions.[21] A good knowledge of the regulatory requirements of generic medicines might have a positive impact on the promotion of such drugs.

More than half of the participants (57%) agreed that a generic medicine must contain the same dose as the brand name medicine and it was lower than the studies from Ethiopia and Australia in which 64.35 and 84.1% has the knowledge that generic medicine must contain

the same dose as the brand name medicine.[13,22] All generic equivalents of brand-name drugs have the same amount of active ingredients; however, they may differ in their color or shape, inert binders and fillers and the specific manufacturing process.[23] The community pharmacists need proper education regarding this issue. The stakeholders and policymakers must work together to implement educational programs.

More than two-thirds of the participants (72%) believed that generic medicines produce more side effects compared to brand-name medicines. In contrast to this, a lower percentage of participants believed that generic medicines produce more side effects compared to brand name medicines in other studies.[6,14]

Nearly half of the participants (48%) supported that the quality of brand-name medicines is required to meet higher safety standards than generic medicines. Similar results were also reported in an Ethiopian study.[13] In contrast to this, 62.5% trusted that brand-name medicines are required to meet higher safety standards than generic medicines in a study conducted in Saudi Arabia.[14] The difference of these findings might be the result of the difference in the educational level of the participants. The investor has to perform a lot of laboratory and clinical tests to establish safety and efficacy for brand-name drugs; however, this is not required for the generic equivalents. Community pharmacists need to made aware of this issue.

Only 63.7% of participants agreed that generic medicines are manufactured after the patent expiry of the originator/innovator brand. A generic drug is usually manufactured without a license from the original innovator. A generic drug product hits the marketplace after the expiry of all patent and marketing exclusivity rights of an innovators product.[17]

In our study, 90% of participants agreed that generic medicines are cheaper than original brand medicines. In contrast, a lower percentage of the participants agreed to the statement in other studies.[13,22] Introduction of generic medicines to the market has led to a reduction of healthcare costs and better access to medicines and healthcare for patients in general.[24] Generic medicines cost less than brand-name medicines because the manufacturers have not spent money on research and development of the medicine, or buying the rights to sell it. Pre-clinical and clinical testing are not required to repeat again for generic medicine. This legislation was approved deliberately with the intention that generic medicines would be cheaper than the equivalent originator medicine because innovation, preclinical and clinical studies are omitted.[25]

Perception of the generic medicine among the community pharmacists

The majority of the participants (87%) opined that they need a standard guideline for both prescriber and pharmacist on brand substitution process and it was similar to the reports of a Saudi Arabian study.[14] This might be due to the lack of a national guideline on generic medicine in our country. National guidelines on generic medicine for community pharmacists should be formulated and implemented to guide them on how and when to make a brand substitution for the consumers that would additionally encourage the use of generic medicines and maintain accessibility and affordability of medicines. More than four-fifths of participants believed that the use of generic medicine among patients can be increased if both the prescriber and the pharmacist work together. A similar finding was reported by Syed et al.[14] Most of the participants may believe that prescriber may not want to a substitution of the prescribed drug by its generic equivalents. Therefore, coordination between prescribers and community pharmacists is required to promote generic medicines. Almost all participants believed that advertisements done and incentives given by the brand drugs manufacturers will influence the prescribing as well as dispensing pattern of brands rather than generic medicines. In contrast to this, only two-thirds of participants agreed to the above statement in other reports.[14] The difference might be due to the greater influence of drug promotion in developing countries. Most of the participants opined that they need more information on the issues relating to the safety and the efficacy of generic medicine in order to dispense it. Workshop and continued pharmacy education should be organized to make the community pharmacists aware of the latest policy on generic medicines.

Limitations: The sample size was small and the response rate was low. As the study was conducted in only Dharan, caution should be exercised when generalizing to other cities and regions in Nepal. Moreover, the use of a self-administered questionnaire could affect the responses as it may be subjected to response or recall bias of the participants.

CONCLUSION

Our study showed that most of the community pharmacists had adequate knowledge and positive perception regarding the many aspects of generic medicine. Pharmacists need to be continuously educated about generic medicine which ultimately leads to its promotion. Most of the participants demanded formulation and implementation of a national guideline on generic medicine for community pharmacists. Encouraging substitution with generic medicines in developing countries would provide a better opportunity for reducing expenditure on healthcare. The study findings would assist policymakers and stakeholders to implement and strengthen the policy regarding the promotion of generic medicines.

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