INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

PHARMACY PROFESSIONALS KNOWLEDGE, ATTITUDE, AND PRACTICE ON GENERIC MEDICINE AT TERTIARY CARE HOSPITALS

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Article Received on: 24/01/20 Approved for publication: 14/02/20

DOI: 10.7897/2230-8407.110327

ABSTRACT

Health care expenses are booming now a day. India is one of the biggest generic medicine manufacturers all over the world. Less knowledge of generic medicine correlates to less prescribing and dispensing of generic medicine. As a pharmacist play an important role in providing a safe and effective medicine to the patient, so they required great knowledge and attitude towards generic medicine. The main objective is to assess the Knowledge, Attitude, and Practice (KAP) of generic medicine among pharmacists in Tertiary Care Hospital, Nashik. This is an observational, cross-sectional, KAP questionnaire-based study carried among 130 pharmacy professionals. The collected data were analysed using descriptive statistics. More than half of the total number of participants (n = 130) had answered general knowledge questions about generic medicines correctly. Attitude study among pharmacy professionals showed that most of them had great knowledge about safety, efficacy but they were neutral attitudes viz and they didn't have perfect idea and were not sure about the manufacturing standards of generic medicines. Most of the pharmacists dispense an innovator drug over generic medicine available (53.84%). The maximum number of pharmacists had never read articles that compared the safety and efficacy of generic versus innovator medicines (61.53%). Our study shows that pharmacists had good knowledge and a positive attitude towards generic medicine but the practice was comparatively poor.

Keywords: Generic medicine, Knowledge, Attitude, Practice, Pharmacist.

INTRODUCTION

A generic medicine is a drug with the same active chemical substance as in the innovator's brand name formulation. A generic drug has the same Active Pharmaceutical Ingredient (API) as in the patented innovator's formulation. They should be comparable to their brand name counterparts, concerning pharmacokinetic and pharmacodynamic properties. After patent expiry (20 years' time period of a patent in India) of innovator brand drug; the monopoly of the patent holder on the drug sale licensing ends. The very next day generic drugs can come in the market with the approval of equivalence between generic and innovator drugs. For this, the regulatory approval of the equivalence should be in hand of the generic manufacturer before the date of the expiry of the patent of innovator brand drug. The demonstration of equivalence has to be proved with bioavailability and bioequivalence studies. They are not needed to repeat preclinical and clinical testing again.[1]

Once generics enter the market, competition often leads to substantially lower prices of both the innovator brand drug and its equivalents. Generally, generics are labelled with the name of the manufacturer and generic International non-proprietary name (INN). In India, pharmacists are not legally empowered to sell generic medicines in place of innovator medicines because patients should have the freedom to choose generic or innovator drugs according to their affordability and pharmacist do not force the patients to take generic medicine until and unless they want to obtain it. Food and Drug Administration (FDA) and National Health Service (NHS) defined 'branded generics' as 'Products that are either novel dosage forms of off-patent products produced by a manufacturer that is not the originator of the molecule or, a molecule copy of an off-patent product with a trading name.'[1]

The major advantage of generic medicine use is cost-benefit. Sometimes adherence to the treatment schedule by the individuals gets influenced by more costly medications, particularly when there are numerous repetitions prescribed by the doctor. Having no knowledge of likenesses and contrasts between generic and branded medicines leads the purchaser to a confused and anxious state causing the major inconvenience of generics. A generic medicine may taste, look and be packaged differently but it has the same active ingredient as the branded medicine. Hence taking the two medicines will lead to an overdose of that particular medicine. Therefore, this should be remembered that one replaces or is substituted for another.[2,3]

To further alleviate the condition of the poor and help them to attain a better quality of life through access to quality medicine the Indian government had started a project named Jan Aushadhi in November 2008 which helps in all the way to set up generic medicine stores. In November 2016, it was again renamed as "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" (PMBJP).[4-6]

A KAP survey means Knowledge, Attitude and Practice. It is a quantitative type method with predefined questions that provides access to quantitative and qualitative information. Inaccurate or insufficient knowledge of pharmacy professionals about generics causes hesitation in the use of these medicines because most healthcare professionals are not sure about the quality of generic drugs and, their efficacy, and this becomes a major obstacle to the wider use of these products. To the best of our knowledge, there

is very little research survey on hospital pharmacists in India to evaluate their knowledge base and practice towards generic medicine. Therefore, to increase the utilization of generic medicine the knowledge about this product will be very necessary. This study narrows the knowledge gap and helps policy maker to make generic prescriptions in future.[6-8] The main objective of this study is to assess the knowledge, Attitude and Practice of Generic Medicine among pharmacists in Tertiary Care Hospital, Nashik.

MATERIAL AND METHODS

This is an observational, cross-sectional study. It was carried out among pharmacy professionals at Nashik, Maharashtra using a pre-validated questionnaire. The study was conducted in compliance with the declaration of Helsinki, ICH-GCP, ICMR and Schedule Y.

A. Study site

The study was performed at medicine dispensaries of the 15 tertiary care hospitals in Nashik, Maharashtra, India.

B. Selection criteria

a) Inclusion Criteria

Pharmacy professionals viz; registered pharmacists who were available during data collection at medicine dispensaries of the tertiary care hospitals.

b) Exclusion Criteria

1. Pharmacists having less than 3 years of working experience.
2. Pharmacists who were not willing to participate.

C. Procedure

A total of 130 pharmacy professionals were sampled by a convenient sampling technique prospectively. Before distributing the pre-validated questionnaire, the subjects informed about the purpose and the course of study. After obtaining written informed consent; the subjects were screened as per inclusion and exclusion criteria. To maintain the confidentiality specific subject code number was allotted. The subjects thus enrolled after the screenings were requested to complete the questionnaires and asked to return it within 30 minutes. The questionnaire consisted of several parts. The first part consists of demographic information of participants (Gender, Age, Qualification, Educational Institute, Working Experience.). The second part consists of 10 knowledge related questions, 10 Attitude related questions, and 3 Practice related questions.

D. Data analysis

The data from collected questionnaires were added to the M.S Excel sheets and was analysed. Descriptive statistics were calculated for the demographic variables of the respondents. Quantitative data were analysed by computing means, percentage. Categorical variables were described using frequencies and percentages.

RESULTS

A total of 130 Pharmacy professionals participated in our study. Out of them, 57.07% were male and 46.92% were female. (Table 1) Other demographic details were described in Table 1.

From all the participants 99 knew that generic medicine can be used in place of innovator drugs. 60 pharmacists said that generic drugs only be marketed after the expiry of the patent of innovator drugs. 110 pharmacists knew that generic drug contains the same active substance as the innovator drug and 70 pharmacists mentioned that generics should be used at the same dose to treat the same disease as innovator medicine. 60 pharmacists had no idea about preclinical and clinical trials are not needed to repeat for generic medicine because they were not aware of these regulatory requirements. 70 pharmacists knew that generic manufacturers only need to do bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator drugs. 95 out of 130 pharmacists knew that generic drugs are not costlier than their innovator drugs. Only 45 pharmacists knew that there was a law made by MCI for doctors that every physician as far as possible prescribes drugs with generic names only. 84 pharmacists were aware of the government of India scheme called Jan Aushadhi whose purpose is to set up generic drug stores around the country. Just 44 out of total participants knew that pharmacists are not legally empowered to sell or purchase generic medicines over innovator medicine. (Table 2)

The results for attitude study among pharmacy professionals showed that most of them had great knowledge about safety; efficacy i.e. Generic drugs have the same safety, efficacy and duration of action as life innovator medicine. A generic drug should be manufactured by the same standard of techniques as innovator drugs. But they were neutral attitude viz, they didn't have a perfect idea and were not sure about manufacturing standards of generic medicines. 'Generic drugs produce more side effects than brand name medicine.' disagreed by 62 participants. 55 pharmacists thought that there is a need to conduct a training programme to increase awareness regarding generic drugs among doctors and patients; while 75 thought that there should be a generic medicine store at every government hospital. 90 pharmacists knew that generics are not for poor patients only. 53 pharmacists agreed that the pharmacists should be allowed to perform generic substitution without consulting a prescribing physician; while 60 strongly agreed that patients have the legal freedom to choose generic medicines. (Table 3)

This study shows that most of the pharmacists dispense an innovator drug over generic medicine available (53.84%); because pharmacists may not be allowed to change in a prescription without consulting with physicians. Most of the pharmacists i.e. 64.61% said that they do not switch a patient on innovator drugs to available generic drugs. They gave opinion on that if the physicians are not prescribed generics then the pharmacist does not have any right to change in prescriptions and they also said that physicians also have to write the name of other substitutions in the prescriptions, so the pharmacist give information on that to the patients, therefore, the patients will able to judge for right choice of drug according to their affordability. The maximum number of pharmacists had never read articles that compared the safety and efficacy of generic versus innovator medicines (61.53%). (Table 4)

DISCUSSION

Pharmacists are professionally responsible for dispensing safe, effective and affordable medicine for a patient. For that good knowledge, positive attitude and quality practice for generic medicine are very essential.[6]

Table 1: Demographic details of the Pharmacists

Age	Number of pharmacists	Percentage
Under 30 Years	52	40.00%
31-40 Years	46	35.38%
41-50 Years	27	20.76%
51 -60 Years	05	3.84%
Over 60 Years	00	0.00
Gender		
Male	69	53.07%
Female	61	46.92%
Educational Qualification		
D. Pharmacy	39	30.00%
B. Pharmacy	55	42.30%
M. Pharmacy	36	27.69%
Educational Institute		
Private	70	53.84%
Government	60	46.15%
Working Experience		
Above 3years	31	23.84%
5-10 Years	62	47.69%
11-20years	29	22.30%
Above 20 Years	8	6.15%

Table 2: Generic Medicine Knowledge related questions and Percentage Frequency of Responses

Questions	Yes	No	Don't know
Can generic drugs be used in place of innovator (patented) drugs?	76.15%	14.61%	9.2%
Can generic drugs only be marketed after the expiry date of the patent of innovator (patented) drug?	46.15%	23.07%	30.76%
Does a generic drug contain the same active substance (s) as the innovator (patented) drug?	84.61%	9.2%	6.15%
Is a generic drug can be used at the same dose (s) to treat the same disease (s) as the innovator (patented) drug?	53.84%	23.07%	23.07%
Does a generic drug manufacturer need to repeat the preclinical studies and clinical trials for generic drugs?	23.07%	30.76%	46.15%
Does generic drug manufacturers need to conduct bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator (patented) drug?	53.84%	7.69%	38.46%
Are generic drugs costlier than innovator (patented) drugs?	7.69%	73.07%	19.23%
Is there any law in India which states that every physician should, as far as possible, prescribe drugs with generic names	34.61%	46.92%	18.46%
Are you aware of the scheme of Government of India called Janaushadhi whose purpose is to set up generic drug stores around the country?	64.61%	18.46%	16.92%
Is the pharmacist legally empowered to sell generic drugs in place of prescribed innovator (patented) drugs?	24.61%	33.84%	41.53%

Table 3: Generic Medicine attitude related questions and percentage frequency of Responses

Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Generic drugs are not as safe as innovator (patented) drug	2.3%	3.8%	23.07%	63.07%	7.69%
Generic drugs are not as effective as innovator (patented) drug	1.53%	4.61%	32.30%	53.84%	7.6%
Generic drugs have a longer duration of action in comparison to innovator (patented) drug	3.84%	11.53%	13.84%	47.69%	23.07%
Innovator (patented) drug is made in modern manufacturing facilities and generic drugs are often made in substandard manufacturing facilities	3.84%	5.38%	61.53%	23.07%	6.15%
Generic drugs produce more side effects than brand name medicines	10.00%	15.38%	7.6%	47.69%	19.23%
Do you think that there is any need for a training program to increase the awareness regarding generic drugs among doctors and patients	3.84%	42.30%	12.30%	26.15%	15.38%
Do you think that there should be a generic medicine store at every government hospital	16.92%	57.69%	15.38%	6.15%	3.84%
Generics are meant only for poor	0%	0%	0%	30.76%	69.23%
Pharmacists should be allowed to perform generic substitutions without consulting prescribing physicians	25.38%	40.76%	17.69%	11.53%	4.61%
Should patients be legally given the freedom to choose a generic drug	46.15%	23.07%	15.38%	7.69%	7.6%

Table 4: Generic Medicine Practice-related questions and percentage frequency of Responses

Questions	Yes	No
Do you dispense innovator (patented) drug over the generic drug available?	53.84%	46.15%
Have you ever switched a patient on innovator (patented) drug to available generic drugs?	35.38%	64.61%
Have you ever read an article on a comparison of the safety and efficacy of generic versus innovator (patented) drugs?	38.46%	61.53%

India has developed a strong capability in producing quality generic medicine and branded drugs in most of the therapeutic categories.[9] However, still, there are overburdened healthcare expenses on poor peoples in the country. Accordingly, our government had taken some steps to enable a key objective through the Jan Aushadhi Scheme of ensuring the availability of quality medicines at an affordable price to all.[10]

Due to generic drug have not passed from these clinical trials, there were saving of billions of rupees. Moreover, innovator drugs were already in the market, so generic medicine requires less marketing. Hence generic drugs are less costly than innovator drugs. Our study shows that 73.07% of participants have a great idea about these.[3] Officials by the government as above and regulatory aspects as per mentions were known by pharmacy personnel in our study. Another such knowledge attitude and practice (KAP) of generics in pharmacy professionals' studies in Palestine and Northern Ethiopia in 2017 only concluded similar results. Most of their pharmacists had basic knowledge concerning generic medicine. Also, professionals with more experience in the sector had a better view of generic products.[8] But some other studies showed a knowledge deficit about generic medicines. One of them was the study in Saudi Arabia in the Makkah region conducted between February and March 2016. They also concluded that 'Healthcare policy makers need to improve awareness about the safety and efficacy of generic medicines and promote their use to cut down the cost of medicines and overall healthcare expenditure'.[11] Another one was the study in South Gujarat, India by Kirtida R Tandel, *et al*; in the year of 2018, concluded that the teaching faculties had knowledge of generic medicines but there was a gap in knowledge and perception of generic and branded drugs.[6]

In India doctors as well as pharmacists have less awareness about generic medicine, so pharmacists agree that there should be some training sessions for doctors, pharmacists as well as patients about the awareness of generic medicine. It would clear the doubts or myths about generic drugs and that ultimately would increase the use of generic drugs. It helps to build up confidence in physicians, patients, and pharmacists as they are always aware of information on generic drugs. This ultimately leads to an increase in generic drug prescribing and dispensing. In our India most of the poor patients approach the government hospital, so every government hospital should provide safe, effective and affordable medicines and health care services to the patients, to achieve World Health Organization's health policy. In our study, most of the participants agreed that there is a need to set up a generic medicine store at every government hospital. Similar conclusions related to the increasing rate of generic medicines, training programme, organization of workshops were drawn by questionnaire-based survey study in Solapur, Maharashtra by Ujwala P Gawali, *et.al;* in 2018.[12]

According to our study, most of the pharmacists were neutral for the attitude related to knowledge of the practical situation of manufacturing standards of generic medicine. Based on the same point, a KAP study in India by Jyoti R Patil and *et al*; in 2016 concluded that practitioners were strongly in favour of generic substitution; concerns regarding their quality standards were discouraging them from doing the same. They also mentioned about The government can play a major role by improving the standard operating procedures for manufacturing the generic drugs thereby assuring the practitioners about their quality.[13]

Limitations

The study was the questionnaire-based survey; so recall bias could occur.

CONCLUSION

Overall, this study shows that pharmacists had good knowledge and a positive attitude towards generic medicine but the practice was poor. The major concern was awareness, which should be increased through regular training programmes such as workshops regarding generic medicine information, continued medical education on generics. Moreover, the guidelines or laws regarding generic medicines should be strengthened and made easily accessible via official websites, webinars so that the patient's physicians and pharmacists always remain aware of information on generic medicine.

ACKNOWLEDGEMENTS

The authors are thankful to all the participants for being a part of this study.

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Cite this article as:

Prashant P. Shivgunde *et al*. Pharmacy Professionals Knowledge, Attitude, and Practice on Generic Medicine at Tertiary Care Hospitals. Int. Res. J. Pharm. 2020;11(3):35-39 http://dx.doi.org/10.7897/2230-8407.110327

Source of support: Nil, Conflict of interest: None Declared