

Review Article

Generic prescribing in India: a stumbling block

Sukhpreet Kaur*

Department of Pharmacology, Dasmesh Institute of Research and Dental Sciences, Faridkot, Punjab, India

Received: 23 June 2020

Accepted: 30 July 2020

***Correspondence:**

Dr. Sukhpreet Kaur,

E-mail: drsukhpreetchd@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

In India, there is 62% out-of-pocket health expenditure per capita and only 15% are covered by health insurance. The use of generics can save a lot of money which can be used for other health issues. But lack of knowledge about cost effectiveness of generic medicines among various health-care professionals had led to a low rate of generic medicine prescription in India. This review aims to identify the barriers in adoption of generic prescribing in clinical practice in India. A systematic literature review was conducted using various healthcare databases such as PubMed and google scholar. The literature search using various combination of keywords retrieved 2360 articles. After excluding duplicates, articles in languages other than English and based on relevance to subject only 15 articles were selected. The barriers to generic prescribing identified from reported literature can be broadly classified based on stakeholders of healthcare setting such as physicians, patients, pharmacist and government policies. The major barriers to generic prescribing identified were negative perception of various stakeholders, lack of awareness of regulatory standards, maturity of health care system, vulnerability of patients, lack of standard guidelines in brand substitution, incentives and influence of drug advertisements. In Indian set up, studies on impact evaluation of generic prescription, emphasizing the quality and cost saving by their use in clinical practice should be conducted. This evidence will help to build the confidence of various stakeholders towards implementing generic prescribing in clinical practice.

Keywords: Barriers, Cost saving, Dental practitioners, Generic prescribing, Negative perception

INTRODUCTION

The globally increasing expenditure on health-care is one the major concerns for the health-care system. In developing countries out-of-pocket expenses are as high as 80% of the total health-care expenditures reported by World Health Organization.¹ The cost of medicines is one of the main concerning components of that spending. Hence, it has become essential to keep healthcare costs trifling without hindering the access to quality care.² The increased consumption of generic medicines can improve the accessibility of health care to the population with limited available resources without any compromise in the quality of care.³ Generics medicines are substitutes for innovator (branded) medicines with the same quality, safety and efficacy. The price of generic medicines is usually 10-80% lower than their innovator equivalent.

This can be helpful for the government and healthcare payers to cover ever-increasing healthcare costs.⁴ In India, the major challenge is to provide high-quality health-care system to the massive population with restricted accessible resources. This can be done by increasing consumption of generic medicines. This will a major breakthrough in improving accessibility of the health care without any compromise in quality.⁵

Indian scenario

India is among the highest per capita out-of-pocket healthcare expenditure country. Hence, generic prescribing can save a lot of money of the payers. Medicines are major constituent of total health expenses-rural areas (72%) and urban areas (68%).⁶ In 2014, National Sample Survey Office reported that overall,

many countries have significantly increased usage of generic by introducing various policies and regulation amendments. In Indian set up there have been two major initiatives by policy makers of India have been Medical Council of India (MCI) amendment in code of conduct for doctors and opening of Jan Aushadi Stores.⁶

In 2018, the Medical Council of India, an amendment was made in the code of conduct for doctors who recommended that every physician should prescribe drugs with generic names.⁶ Moreover, the department of pharmaceuticals, Government of India, started an initiative “Jan Aushadi”. The aim of this program is to provide medicines to poor people in country at a reasonable and affordable price without compromising the quality. Until 2018, 3200 Jan Aushadi stores are functional in India but still these are not enough to meet requirements of the Indian population.⁷

Despite all the initiatives, generic prescribing is not very adopted in Indian scenario. The market share of branded medicines is 90% of the Indian domestic pharmaceutical market which is approximately Rs.1,00,000 crore and more.⁸ As India is one of the major producers and exporter of generic medicines in world, it reflects that enough generic name equivalents of branded medicines are not sold in Indian market. Moreover, fixed dose combinations hold a major share of approximately 45% of the market (45,000 crore), half of which are irrational.⁹ This article identifies barriers in adoption of generics prescribing in clinical practice in India.

REVIEW OF LITERATURE

A systematic literature review was conducted find the barriers to generic prescribing in India. The literature review was conducted using various healthcare databases such as PubMed and Google Scholar. The combination of various keywords was used for literature search. The keywords used were generic prescribing, generic ANDA prescribing, generic ANDA medicines, India, barriers, perceptions. The studies with key findings focusing on barriers in adoption of generic medicines in clinical practice were included in this study.

The literature search using various combinations of keywords retrieved 2360 articles. After excluding duplicates and scanning through the title, based on relevance to subject 49 articles were shortlisted. From these 49 articles, 6 articles were excluded as full manuscript was not in English. Out of remaining 43, only 15 articles were selected and others were excluded as they do not study barriers to adoption of generic medicines in clinical practice. Details of articles included in review of literature are shown in (Figure 1).

The 15 studies which were included in review of literature, represented data from various developed and developing countries. There were two major types of studies included: one was review of literature and second

was surveys conducted among various stake holders to find their knowledge and perception on Generic Prescribing.

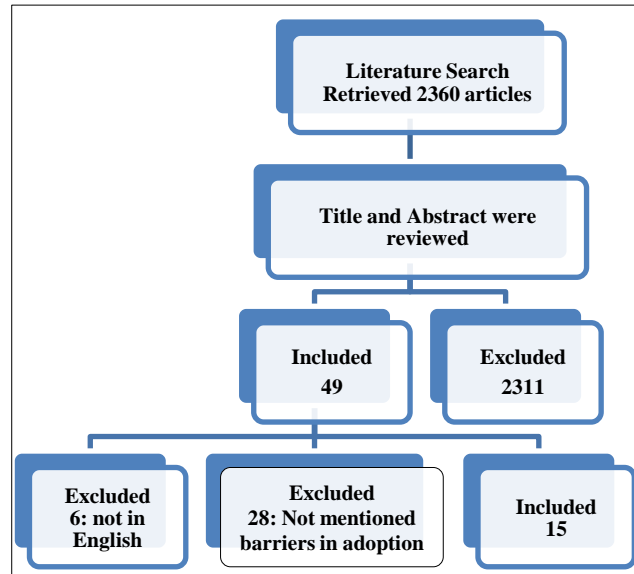


Figure 1: Details of literature search conducted.

Various barriers to generic prescribing identified from reported literature can be broadly classified based on stakeholders of healthcare setting such as physicians, patients, pharmacist and government policies. Barriers to the generic prescribing are shown in (Figure 2).

Physician

The successful implementation of any policy or product is dependent on the confidence in effectiveness, safety and quality of it. There have been various studies showing that perception of physician about the generic medicines have been one of the major barriers in adoption of generic prescribing. A nationwide survey in Malaysia showed that the physicians have negative perception about the generic medicines. Nearly 52% agreed that generic medicines are less effective than reference medicine. Further, 74.2% of the physicians believed that generic medicines do not have high standards of manufacturing and quality control as compared with branded products.¹⁰ Another study from Bosnia and Herzegovina reported similar results 60% respondents agreed that production of generics is in poorer conditions.¹¹ One more review conducted in United States of America reported that physicians were apprehensive about using generics for themselves and family because of their concerns over the safety and efficacy. Further, lack of awareness of the regulatory standards is another deterrent from using generic in clinical practice.¹² Any sort of interaction with pharmaceutical industry such as detailing by representatives or provision of free samples is also responsible for increased brand prescribing even if generic versions of that medicine are available.¹³

Another systematic review reported that perception of physician is dependent on the maturity of healthcare system. The physician in less mature healthcare system report large variations regarding requirement of bioequivalence and quality of standards for manufacturing generics.¹³ In Ireland, study was conducted after the Health Act 2013 legislated generic substitution. This study highlighted the apprehensions about the

generic switch in vulnerable patient groups such as frail, the aged, using polypharmacy, with cognitive impairment and anxious.¹⁴ This is also supported by another study conducted in Switzerland where physicians were reluctant to switch to generics because of certain uncontrollable factors like deterioration health status of patient because of aging, multiple illness and complex treatment regimens.¹⁵

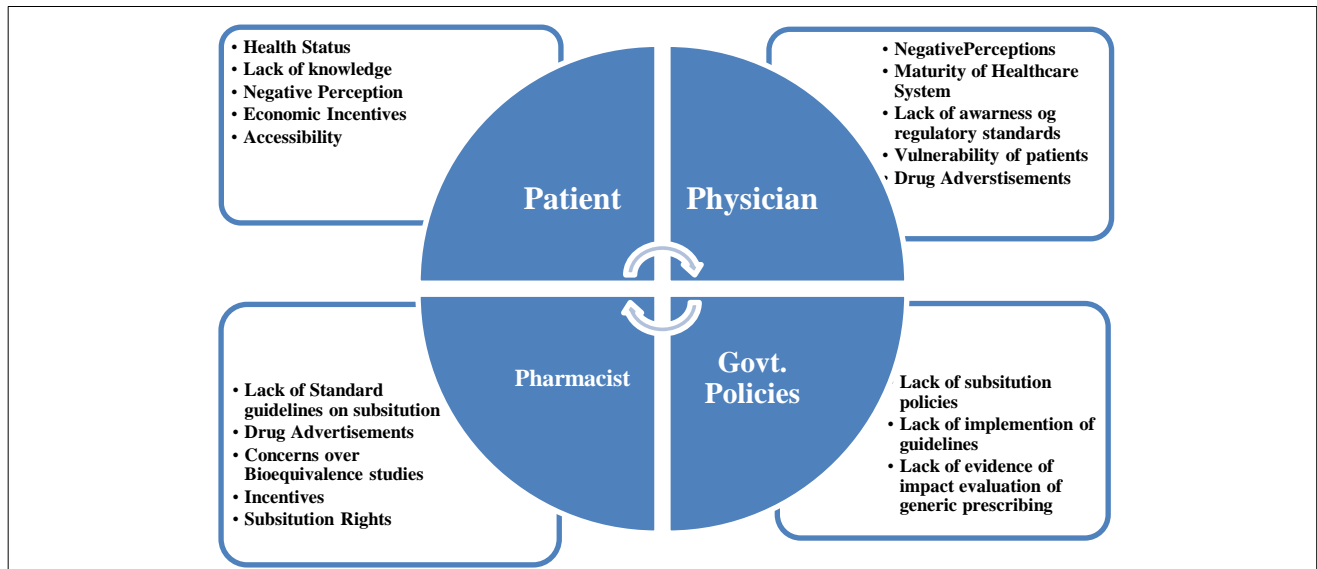


Figure 2: Barrier to generic prescribing.

An Indian study, using various tests showed the generic and branded were of comparable quality. On contrary to quality tests, negative perception of medicine quality along with other factors contributes towards more expensive medicines being prescribed. This explained that the trust in health system is the dominant factor which governs the choice of medicines and providers within the health care system.¹⁶ Similarly, another study conducted in South Africa presented major difference between perceptions of quality and actual quality of medicines. This indicates that there is lack of initiatives by government to spread awareness regarding quality tests of generics and building up the trust of prescribers.¹⁷

Drug advertisements by manufacturers also emerged as one of the factors influencing the prescribing/dispensing practices. A survey conducted in Ethiopia reported 39.9% physicians (70.6%) strongly believed that their prescribing practices are influenced by drug advertisements and promotion by the manufacturers.¹⁸

Pharmacist

A multistakeholder study conducted in Ethiopia showed that the 87.2% pharmacist agreed that standard guidelines to pharmacist are required on brand substitution process

and also, drug advertisements and promotion by the manufacturers influences their prescribing practice.¹⁸ Another Irish study reported that 84% pharmacist supported generic substitution and showed concerns over issue of bioequivalence, computer software used for prescribing and implementation of the policies regarding generic prescribing.¹⁴

A review conducted by Toverud et al reported 8 studies conducted among pharmacist to study their perspective regarding use of generic medicines. This study showed that the maturity of their healthcare system is one the major factor influencing perception of pharmacist about generic medicines. The pharmacist showed concern about the trustworthiness of manufacturing sources, inferior regulatory and control processes, narrow therapeutic window, special category patients (like elderly, polypharmacy cases, mentally ill) and quality of product.¹³

Patient

A study conducted by Patel et al reported that the knowledge of consumers about the generic medicines is not enough. In case of self-medication usually rely on familiar brand as they have used it before and for

prescription drugs, they rely on the advice of their prescriber rather than the dispenser. The cost of medicine is an important factor for patients who suffer from chronic illness and it is reported that acceptability of generics is more in this set of patients. A study reported that in Johannesburg consumers believed that generic medicines were inferior and referred then as “*fong kong*” a term used to describe fake goods.¹⁷ Nguyen et al. also reported similar patient perceptions and stated poor acceptance in patients due to dearth of knowledge of generic medicines and fallacies that discount price means discount quality.¹⁹

Another study conducted showed contrasting results, majority of patients were familiar with generic medicines (84%) and almost half of them had experienced switch to a generic in past. But this lead to confusion and anxiety in patients because of major changes in packaging, shape and appearance compared to their medicines which they were already using.¹⁴ Another Irish study reported that the physician were positive towards the generic prescribing but were concerned for their patients capacities to deal with the confusing changes in their medications.²⁰

A study conducted in Ethiopia showed that almost half of patients (56%) were aware of the term branded and generic medicines and 38.7% of patients strongly believed that branded medicines are more efficacious. Almost half of patients believed that they should have the option of choosing between generic and brand medicines and 61.4% of patients wanted that cost should be considered before a medicine prescribed.¹⁸

Government policies

In developing countries, the prescription written by the doctor has a significant influence on the usage of generic medicines as the patients or relatives do everything that can be done to buy precisely what is prescribed.²¹

Hassali et al reviewed eight countries with developed healthcare infrastructure to study role played by generic medicines and the policies to promote generic prescription. It was observed that each country policy designed and suited to their health care system. Such as in US generic substitution, generic prescribing in the UK and mandatory generic substitution in Sweden and Finland.²² To efficiently and successfully implement the generic prescribing policy, different balancing sub-policies and initiatives were required depending on the healthcare system of the country. The commonly reported obstacles for generic prescribing are negative perceptions about generic medicines, lack of a clear generic medicine policy, availability of information about generic medicines to both healthcare professionals and patients, brand substitution guidelines, regulations for generic substitution by pharmacists, and incentives to all healthcare professionals and patients.²²

Kaplan et al, studied the literature on generic policies in low and middle income countries (LMIC). The authors noted that as compared to high-income countries (HIC) that literature on impact of medicine policies promoting generic prescribing is understated. As LMIC are dependent on donations, funding from health care organizations and have lack of insurance systems, so the data from HIC cannot be translated to LMICs. Lack of evidence does not mean medicine policies promoting generic prescribing are failure in LMICs regardless of impact evaluation. So, proper assessment of medicines policies in LMIC is also one the major barriers in implementing generic prescribing in practice. There is lack of evidence of implementation and impact of policies on health care costs.²³

Another review conducted by Moe-Byrne et al had similar findings that the current evidence remains inadequate to determine which behaviour change or intervention or combination of interventions is most effective due to methodological weakness and contradictory results.²⁴

DISCUSSION

The initiatives taken at various stake holder levels can definitely improve generic prescribing in India. First of all, it is required that the negative perception about generic medicines should be changed. To bring all change in practice, a positive and adaptive environment is very important. Continuing Education and Training programs will definitely improvise the generic prescribing. It has been reported that continuing education programs help to implement changes in clinical practice.²⁵

Also, it should be noted that there is also a need to incorporate the concept of generic prescribing in teaching programs. The medical students study concept of generic prescribing during second year of their MBBS teachings in pharmacology. After, this significance of generic prescribing in reducing patient expenditure on medicines is never explained in their undergraduate and post graduate training. The medical education curriculum should take into consideration this drawback to ensure forthcoming physicians are well aware and confident in generic prescribing.²⁶ Education about the generics will build up the confidence of medical fraternity and will lead to development of habit of generic prescribing.^{27,28}

A survey conducted by Gawali et al showed that only 42% medical practitioner were aware that generic medicines are bioequivalent to innovator product.²⁹ The evidence and education particularly in areas of bioequivalence and regulatory aspects will help in dismissing myths, fears, doubts and untrue ideas about generic medicines. This will be an important step to overcome the negative perception about generic medicines.

The regulatory authorities should follow stringent rules to ensure uniform quality of generics by formulating rules for pharmaceuticals manufacturers. Taking this into consideration, in 2016 guidelines were formulated which stated that there should be 90% confidence interval of generic drug to branded drug for key pharmacokinetic parameters (such as maximum concentration C-max and Area under curve to lie between 80% and 125%).³⁰ Bioequivalence studies are required for the regulators to ensure that the pharmaceutical equivalent reference product is therapeutically equal to standard reference product.

Pharmacies other than in government-run hospitals and clinics hardly stock unbranded generic drugs. In such a situation if generic is prescribed the pharmacist would dispense the brand which usually is available or the favourite brand. This becomes then discretion of the pharmacist that what is being dispensed in case of non-availability of generics drugs. If compulsory prescription and dispensing of generic is enforced, for that the physicians should be positive and confident about quality of generics. Without the support of regulatory authorities ensuring quality of products. This positive attitude and confidence towards generic prescribing is not possible.³⁰

Physician and pharmacist are responsible for the medications being consumed by the patients. In many countries like USA, Australia and northern Europe generics in general offered to patients from all socioeconomic backgrounds. But there re-certain patient categories for whom switching to generics or switching between generics is not recommended. Those are the patients in which confusion may arise. These are usually elderly patients, polypharmacy user or mentally ill patients.

Given all these issues, it is clear that this cannot be implemented in practice until all stakeholders at their own capacity contribute towards the successful implementation of the generic prescribing. A robust medicine regulatory system in which all stakeholders have belief is being implemented. Also, the availability of generic medicines in all types of pharmacies is there. The financial incentives among all involved in prescribing cascade are there including prescriber, pharmacist and patients. This will enhance uptake of generic prescribing in countries like India where is an absence or scarcity of health insurances and out of pocket expenses of medicines are bourn by the patients themselves.

It can be concluded that successful implementation of any policy is merely an anecdote until robust evidence based studies are available to support the facts. Hence, there is a need conduct studies on consumption of generics emphasizing the quality and cost saving by their use in clinical practice. Only after real-time effectiveness of generic drugs is documented and made published, will physicians be able to easily convince patients, including the wealthy, to take generic drugs. The Indian

government can only achieve this goal by maintain high regulatory standards for safety, efficacy, and quality in the review of generic drugs.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Not required

REFERENCES

1. Jamshed SQ, Hassali MA, Ibrahim MI, Babar ZU. Knowledge attitude and perception of dispensing doctors regarding generic medicines in Karachi, Pakistan: a qualitative study. *J Pak Med Assoc.* 2011;61:80-3.
2. Bakthavathsalam G. Generic drugs: cost effective alternative to branded drug. *Health Administrator.* 2006;19:16-9.
3. Jamshed SQ, Ibrahim MIM, Hassali MA, Masood I, Low BY, Shafie AA, et al. Perception and attitude of general practitioners regarding generic medicines in Karachi, Pakistan: a questionnaire based study. *Southern Med Rev.* 2012;5(1):22-30.
4. Dylst P, Vulto A, Simoons S. How can pharmacist remuneration systems in Europe contribute to generic medicine dispensing? *Pharm Pract.* 2012;10(1):3-8.
5. Singhal AK, Solanki MN, Dave DJ. Perceptions and practice of use of generic medicines by intern doctors at a tertiary care teaching hospital -a cross sectional study". *Saudi J Med Pharm Sci.* 2019;5(11):972-8.
6. Live M. Medicine costs form bulk of out-of-pocket health expenses: NSSO. Available at: <https://www.livemint.com/Politics/30z97MDZDMe wkJHsfM5D6I/Medicine-costs-form-bulk-of-outof-pocket-health-expenses-N.html>. Accessed on 15th May 2020.
7. Thawani V, Mani A, Upmanyu N. Why the Jan Aushadhi scheme has lost its steam in India?. *J Pharmacol Pharmacother.* 2017;8(3):134-6.
8. StayHappyPharmacy. The State of Generic Medicines in India. Available at: <https://stayhappi.in/the-state-of-generic-medicines-inindia/textAtleastofthe, genericnameequivalentsbeingsold>. Accessed on 18th June 2020.
9. Scroll. In. Indian government may ask doctors to prescribe medicines under generic names. Is it practical? Available at: <https://scroll.in/pulse/835207/indian-government-may-ask-doctors-to-prescribe-medicines-under-generic-names-is-it-practical>. Accessed on 18th June 2020.
10. Kumar R, Hassali MA, Saleem F, Alrasheedy AA, Kaur N, Wong ZY, et al. Knowledge and perceptions of physicians from private medical centers towards generic medicines: a nationwide survey from Malaysia. *J Pharma Policy Pract.* 2015;8:11.
11. Catic T, Avdagic L, Martinovic I. Knowledge and attitudes of physicians and pharmacists towards the use of generic medicines in Bosnia and Herzegovina. *Med Glas (Zenica).* 2017;14(1):25-32.

12. Choudhary NK, Denberg TD, Qaseem A. Improving Adherence to therapy and clinical outcomes while containing costs: opportunities from the greater use of generic medications: best practice advice from the clinical guidelines committee of the American College of Physicians. *Ann Intern Med.* 2016;164:41-9.
13. Toverud EL, Hartman K, Hakonsen H. A systematic review of physicians' and pharmacists' perspectives in generic drug use: what are the global challenges?. *Appl Health Econ Health Policy.* 2015;13:S35-45.
14. O'Leary A, Usher C, Lynch M, Hall M, Hemeryk L, Spillane S et al. Generic medicines and generic substitution: contrasting perspectives of stakeholders in Ireland. *BMC Res Notes.* 2015;8:790.
15. Decollogny A, Egli Y, Halfon P, Lufkin TM. Determinants of generic drug substitution in Switzerland. *BMC Health Service Res.* 2011;11:17.
16. Aivalli PK, Elias MA, Pati MK et al. Perceptions of the quality of generic medicines: implications for trust in public services within the local health system in Tumkur, India. *BMJ Glob Health.* 2018; 2:e00064.
17. Patel A, Gauld R, Norris P, Rades T. Quality of generic medicines in South Africa: perceptions versus reality-a qualitative study. *BMC Health Services Res.* 2012;12:297.
18. Gebrosillassie BM, Betachew SA, Tefera YG, Abebe TB, Mekuria AB, Haile KT et al. Evaluating patients', physicians' and pharmacy professionals' perception and concern regarding generic medicines in Gondar town, northwest Ethiopia: A multi-stakeholder, cross-sectional survey. *PloS One.* 2018;13(11): e0204146.
19. Nguyen TA, Hassali MA, McLachlan A. Generic medicines policies in the Asia Pacific region: ways forward", WHO South-East Asia Journal of Public Health. 2013;2(1):72-4.
20. Dunne SS, Shannon B, Cullen W, Dunne CP. Beliefs, perceptions and behaviors of GPs towards generic medicines. *Family Pract.* 2014;31(4):467-4.
21. Hassali MA, Shafie AA, Jamshed S, Ibrahim MI, Awaisu A. Consumers' views on generic medicines: a review of literature. *Int J Pharm Pract.* 2009;17:79-88.
22. Hassali MA, Alrasheedy AA, McLachlan A, Ngugen TA, Al-Tamimi SK, Izham M, et al. The experiences of implementing generic medicine policy in eight countries: a review and recommendations for a successful promotion of generic medicine use. *Saudi Pharmaceutical Journal.* 2014;22:491-503.
23. Kaplan WA, Ritz LS, Vitello M, Wirtz VL. Policies to promote use of generics medicines in low and middle income countries: a review of published literature 2000-2010. *Health Policy.* 2012;106(3):211-24.
24. Moe-Byrne T, Chambers D, Harden M, McDald C. Behaviour change interventions to promote prescribing of generic drugs: a rapid evidence synthesis and systematic review. *BMJ Open.* 2014;4(5):e004623.
25. Cantillon P, Jones R. Does continuing medical education in general practice make a difference?. *BMJ.* 1999;318(7193):1276-79.
26. Kamath A. Prescribing generic drugs using a generic name: Are we teaching it right?. *Ind J Med Ethics.* 2016;1:194.
27. Bhattacharjee P, Das L, Ghosh R, Das UK, Chakraborty M. Knowledge, attitude and practice of generic medicines among doctors in a tertiary care teaching hospital of Tripura, India. *Int J Basic Clin Pharmacol.* 2017;6:1287-92.
28. Gupta R, Malhotra A, Malhotra P. A study on assessment of awareness in generic drugs among doctors in a tertiary care teaching hospital in north India. *Int J Res Med Sci.* 2018;6:1362-7.
29. Gawali UP, Gurung A, Deshkar AT, Sabat SK. Study of knowledge, attitude and practice of prescribing generic medicines by interns, residents and faculty in a tertiary care teaching hospital. *Natl J Physiol Pharm Pharmacol.* 2018;8(12):1631-34.
30. Joshi SS, Shetty YC, Karande S. Generic drugs -The Indian scenario. *J Postgrad Med.* 2019;65(2):67-9.

Cite this article as: Kaur S. Generic prescribing in India: a stumbling block. *Int J Res Med Sci* 2020;8:3426-31.