e-ISSN: 0975-5160, p-ISSN: 2820-2651

Available online on www.ijtpr.com

International Journal of Toxicological and Pharmacological Research 2024; 14 (1); 340-342

Original Research Article

A Questionnaire Based Cross Sectional Study of Knowledge, Attitudes and Practices with Regard to Generic Drugs and Generic Substitution in Interns and Post Graduates in Medical Colleges in & Around Visakhapatnam

D. Annapurna[1], Barla Ajaykumar[2], P. Satya Teja[3], P. Ramu[4]

[1]Professor & H.O.D., Department of Pharmacology, Government Medical College, Vizianagaram, Andhra Pradesh, India

[2]Assistant Professor, Department of ENT, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India

[3]Intern, NRI Institute of Medical Sciences, Sangivalasa, Visakhapatnam

[4]Associate Professor, Department of Paediatrics, Government Medical College, Srikakulam, Andhra Pradesh, India

Received: 05-12-2023 / Revised: 31-12-2023 / Accepted: 10-01-2024

Corresponding author: Dr. P. Ramu

Conflict of interest: Nil

Abstract:

Introduction: Health care costs are rising day by day for which cost of medicines also contributing significantly. Cost of medicines can be reduced by enabling generic drugs to enter the market as they are 30%–80% cheaper than brand drugs. The present study was conducted to evaluate level of awareness, attitude and practices regarding the generic drugs in Interns and Pgs as they are the future practitioners & should have enough knowledge and should be able to educate their patients and clear any doubts about generic drugs . The acquired results of this study will give an overview. Conducting CME programmes to overcome identified knowledge gaps will help in increasing generic prescriptions and decrease prescription costs.

Materials and Methods: A Cross Sectional Questionnaire based KAP Study, was conducted in Interns and postgraduates in medical colleges, in and around Visakhapatnam. Prior permission taken from the IEC, KGH, Visakhapatnam, for the conduct of the study. A structured questionnaire in Google forms distributed through what's App groups. Total 202 completed responses with consent were received and were analyzed by using Microsoft Excel. Data summarized by routine descriptive statistics, and frequency distribution of responses calculated.

Results and Discussion: Most of the Interns and PGs were aware of generic drugs and generic substitution and they have positive attitude towards them. Few knowledge gaps were identified in the areas of requirement of pre-clinical and clinical testing, risks associated with generic substitution in case of drugs with low therapeutic index, drug patents, "Jan Aushadhi" campaign.

Conclusion: Conducting CMEs, Quality assurance of both brand and generic drugs and post-marketing surveillance improve prescription of generic drugs.

Keywords: Generic drugs, Generic substitution, Bio equivalence, Brand drugs, Interns, Post graduates.

Introduction

Health care costs are rising day by day. Apart from cost of Hospital services and Laboratory services, costs of drugs are also rising. One way to reduce drug costs is to enable generic drugs to enter the market as they are typically 30%–80% cheaper than originator equivalents [1]. As per U.S.FDA, generic drugs are defined as "drugs which are bioequivalent and identical to a brand name drug in dosage form, safety, strength, route of administration, quality, performance, characteristics and intended use [2].

Generic drugs may be marketed under the non-propriety name or as a branded generic. Branded generic drugs have names derived from a combination of the manufacturer's name and the non-proprietary name [3]. When a drug is newly developed the pharmaceutical company which develops it will have a patent which give protection for 20 years. However, many countries e.g. the European Union and the USA may grant up to 5 years of additional protection ("patent term restoration") [4]. After expiry of the patent, other

companies also permitted to produce the same drugs which are known as generic drugs.

An abbreviated new drug application (ANDA) to be submitted by pharmaceutical companies to the regulatory authorities for getting approval to market a generic drug. ANDA process does not require the manufacturer to repeat pre-clinical and clinical testing of generics (which is often time-consuming and requires lots of investment) [5]. However Bioequivalence studies need to be done with generic versions. Competition between generic drug manufacturers further contributes to their low prices [6]. Price of generic drugs falls to the ongoing cost of production, which is usually much lower than the monopoly price which is dictated by the innovator company during the period of patent protection [7]. The use of generic drugs can significantly reduce health-care expenditure without compromising the quality or the therapeutic efficacy, hence many countries tried to increase the usage of generic drugs [8]. Our Indian government has launched the "jan aushadhi" campaign under which the first "jan aushadhi" store was opened in Punjab in 2008 [9], since then many stores are established all over the country. The central government also directed all the states/ UT governments to instruct their respective drug licensing authorities to grant/ renew licenses to manufacture drugs in proper/generic names only [10]. The Medical Council of India, in an amendment to the code of conduct for doctors in October 2016, has recommended that every physician should prescribe drugs with generic names [11].

The success of the Generic Substitution policy depends on the attitude of physicians, patients, and pharmacists [12]. Refusal of Generic Substitution by patients can be related to the lack of proper information or access to generic drugs. Physicians should inform their patients about Generic Substitution, ask them about their experience with Generic Substitution, and if needed clarify any misunderstandings [13]. Previously many KAP studies on generic drugs were conducted in general practitioners, general public and pharmacists and in medical and pharmacy students at different places. But there is paucity of such data in junior doctors who are the practitioners in near future. So the present study was conducted in them. The results of this study give an overview and helps in planning orientation programmes to cover any knowledge gaps and to increasing awareness about generic drugs in them. Ultimately this will increase generic prescriptions and decrease prescription costs.

Aims and Objectives

1. To record level of knowledge of inters and postgraduates about generic drugs and to assess their understanding of Generic Substitution.
2. To analyze their attitude towards and their experience with Generic Substitution

Materials and Methods

A Cross Sectional Questionnaire based KAP Study was cconducted in Interns and postgraduates studying in medical colleges, in and around Visakhapatnam, who are willing to participate in the study from February, 2023 to July, 2023.The sample size was calculated using the formula 4PQ/L2, where P=Prevalence/proportion, Q= 1-P, L=allowable error. P is taken as 69% based on the awareness of practitioners about generic drugs from the previous similar study16with 10% margin of error.

The calculation gives a minimum sample size of 180. Prior permission taken from the IEC, KGH, and Visakhapatnam vide s.no. 5/IEC KGH/JAN 2023, dt.24-1-2023, for the conduct of the study. Interns and postgraduates studying in medical colleges, in and around Visakhapatnam, who were willing to participate in the study, and gave online informed consent, were included in the study. Participants who did not give a valid online informed consent and responses with incomplete information for the given questionnaire were excluded from the study. A structured questionnaire was designed in Google forms using the pattern of questions in similar studies [14,15,16] and distributed through their what's app groups repeatedly till the sample size is achieved.

The Questionnaire contains confidentiality statement, consent statement along with instructions to complete the questionnaire. It consists of four sections, questions to collect demographic data in Section-1, in section- 2 questions to test the knowledge of participants regarding generic drugs, section 3 questions to test their attitudes towards generics and section 4 questions to test practices with regard to generic drugs and generic substitution. Completed responses with consent were analyzed by using Microsoft Excel. Data summarized by routine descriptive statistics, and frequency distribution of responses calculated.

Results

202 completed responses with informed online consent were submitted, and were analysed. Among the respondents 92% were between 21-29 years age group, Fig-1 shows age distribution and Fig-2 shows gender distribution. Among the respondents 72(35.6%) were pgs and 130(64.4%) were interns.

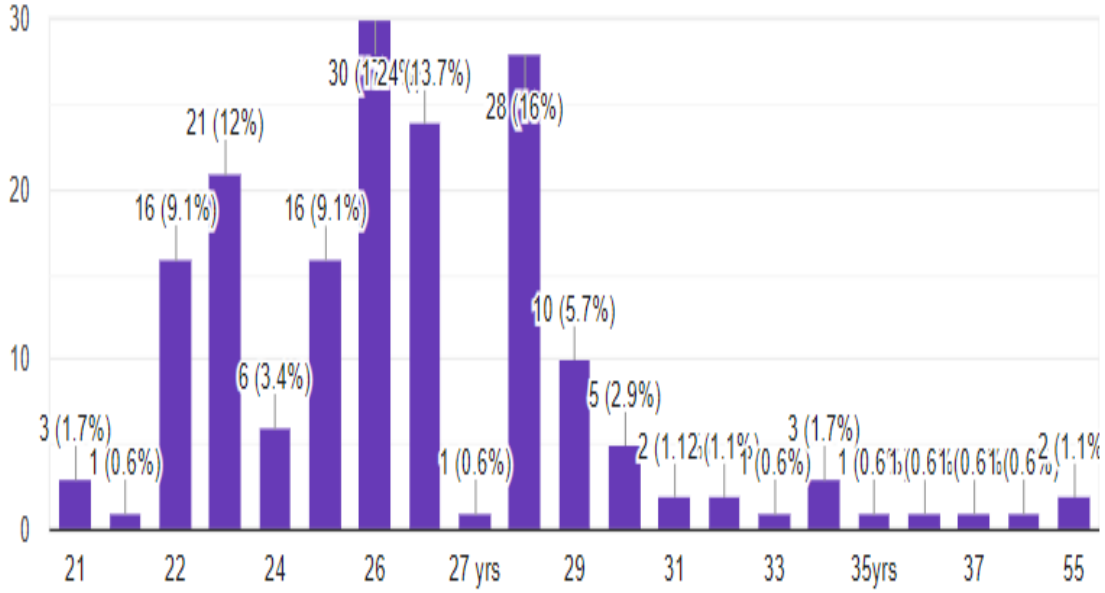

Figure 1: Age Distribution of respondents

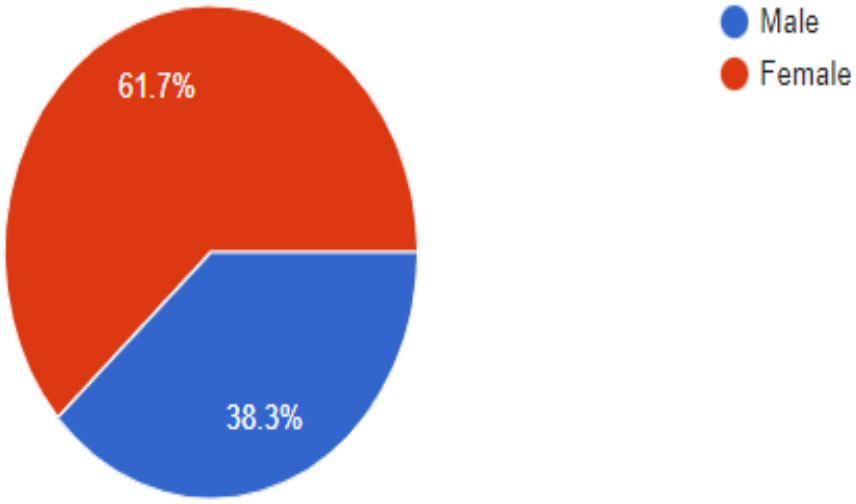

Figure 2: Gender distribution of the respondents

Table-1 summarizes interns and pgs responses to knowledge based questions. Most of the respondents 80.2% (162) were aware that Generic drugs intended to be used in the same dose and dosage form and for same indications as their innovator counter parts, 94.1%(190) know that bioequivalence studies required for generic drugs approval by regulatory authorities, 84.7% (171) know that Generic drugs produced by different companies and 89.6% (181) aware that generic drugs are cheaper when compared to their innovator counter parts. Only 34.2% (69) respondents were aware that Generic drugs marketed after expiry of innovator drug's patent, 11.9% (24) know that preclinical and clinical testing not required for approval of generic drugs by regulatory authorities. More than half of the respondents 57.43% (116) do not have knowledge about all the generic drugs available in the market, 44.1% (89) respondents not aware of "Jan Aushadhi" campaign, 48.5%(98) were not aware that generic substitution for a brand drug may not safe for drugs with low therapeutic index.

Table 1: Responses to Questions to test knowledge

S.No.	Question	Yes Number (%)	No Number (%)
1	Are Generic drugs intended to be used in the same dose and dosage form and for same indications as their innovator counter parts?	162 (80.2)	40 (19.8)
2	Are Generic drugs marketed after expiry of innovator drug's patent	69 (34.2)	133 (65.8)
3	Are preclinical and clinical testing required for approval of generic drugs by regulatory authorities?	178 (88.1)	24 (11.9)
4	Are Bioequivalence studies required for generic drugs approval by regulatory authorities?	190 (94.1)	12 (5.9)
5	Are Generic drugs produced by different companies?	171(84.7)	31(15.3)
6	Are the generic drugs cheaper when compared to their innovator counter parts?	181 (89.61)	21 (10.29)
7	Do you have Knowledge about all generics available in the market?	116 (57.43)	86 (42.57)
8	Are you aware of "Jan Aushadhi" campaign, launched by Indian Government?	113 (55.9)	89(44.1)
9	Are you aware that generic substitution for a brand drug may not safe for drugs with low therapeutic index?	104(51.5)	98 (48.5)

As far as attitudes(Table: 2) are concerned 86.6% (175) respondents believe in generic substitution, 83% (166) believe that generics are as safe & effective as innovator drugs, 95.5% (91) said that generics are more affordable and 95.5% (193) were opined that patients should have liberty to choose generics over Brand drugs. Among participants 97.5% (197) have positive attitude towards educating patients to build confidence in generics and 94% (188) of them opined that Importance of generics should be taught in early part of MBBS curriculum, another 96.5%(195) were opined that every hospital should have generic store. Almost all 99.5% (200) were of the opinion that there should be a National level generics online reference. Only 38.1% (75) respondents opined that onset of action is late with generics.

Table 2: Responses to Questions to test Attitudes

S.No.	Question	Yes Number (%)	No Number (%)
1.	Do you believe in generic substitutes?	175 (86.6%)	27(13.7%)
2.	Patients should have liberty to choose generics over innovator	193 (95.5%)	9(4.5%)
3.	Patients should be educated to build confidence in generics	197(97.5%)	5(2.5%)
4.	Importance of generics should be taught in early part of MBBS curriculum	188 (94%)	14 (6%)
5.	There should be generic store in every hospital	195 (96.5%)	7(3.5%)
6.	National level generics online reference should be made available	99.5%(200)	2(0.5%)
7.	Generics are as safe & effective as innovator drugs	166 (83%)	36(17%)
8.	Generics onset of action is late when compared with their innovator	75(38.1%)	127(61.9%)
9.	Generics are more affordable than brand name drugs	191(95.%)	11(5%)

As far as practices (Table: 3**)** are concerned 77.7% (157) said that they prescribe generics for themselves or to their relatives, and 81.7% (165) respondents said that they prescribe generics for their patients. Only 26.7% (54) respondents said that they prescribe generics in all diseases. Only 34.2% (69) read articles on safety and efficacy of generics v/s brand drugs. Majority of respondents 74.3% (150) said that they allow generic substitution for brand drugs in their prescription by pharmacist. Majority of respondents 86.1% (174) said they were influenced by Patient demand or financial status in prescribing generics. Only 31.2% (63) said that medical representatives or pharmacy people influence their prescription.

Table 3: Responses to Questions on practices

S. No.	Question	Yes Number (%)	No Number (%)
1.	Do you prescribe generics for yourself or your relatives?	157 (77.7%)	45 (22.27%)
2.	Do you prescribe generics for your patients?	165 (81.7%)	37(18.31%)
3.	Do you prescribe generics in all diseases?	54 (26.7%)	148(73.3%)
4.	Do you read any articles on safety and efficacy of generics v/s brand drugs?	69 (34.2%)	133 (65.8%)
5.	Do you allow generic drug substitution in place of branded drugs in your prescription by pharmacist?	150 (74.3%)	52(25.7%)
6.	Patient demand or financial status influence you in prescribing generics?	174 (86.1%)	28(13.9%)
7.	Medical representatives or pharmacy people influence your prescription?	63 (31.2%)	139(68.8%)

Discussion

In our study majority of Interns and Pgs had good knowledge about generics. The regulatory guidelines state that generic drugs must be therapeutically equivalent and functions in the same way as innovator (brand) drugs. Majority of participants in this study know that generic drugs are intended to be used in the same dose and dosage form and for same indications as their innovator counter parts (80.2%).

Various studies have reported that generic medicines function equivalently to their innovator counter parts [17]. In the Present study most of the participants know that Bioequivalence studies required for generic drugs approval by (94.1%), and most of them (61.9%) were rightly not agreed that their 'onset of action is late when compared to brand drugs. An assessment of bioequivalence data submitted to the US Food and Drug Administration, from 1996 to 2007, showed that the generic medicines did not differ substantially from their innovator counterparts [18].

Various studies have reported that starting the therapy with generic medicines or switching to generic medicines is not related with poorer efficacy or safety [19, 20] .In the present study majority participants know that generic drugs are cheaper (89.61%) and more affordable (95%) and produced by different companies (84.7%). Only 11.9% know that preclinical and clinical testing do not required for approval of generic drugs which will contribute to lesser price as pre-clinical and clinical testing requires lots of investment and also time. Lower price of generics, may raise doubt about their efficacy, safety, and quality [21]. But for approval of generic drugs, strict regulations required to be fulfilled with respect to identity, strength, quality, purity, potency, compliance to the GMP guidelines and the manufacturer need to submit detailed information about the facilities used for production, packaging, labelling of the generic drugs to the regulatory body [21, 22].

The FDA applies the same standards for all drug manufacturing facilities, and many companies manufacture both brand and generic drugs. In fact, the FDA estimates that 50% of generic drug production is by brand-name companies. Hence such doubts about efficacy, safety, and quality of generic drugs are baseless. In the present study majority of participants believe in generic drugs and generic substitution (86.6%) and about 83% opined that generics are as safe & effective as innovator drugs. Encouraging the widespread use of generic drugs will reduce price of brand drugs also by increasing competition in the market and results in availability of medicines to a larger population at affordable prices and contribute to reduction in overall health care expenditure in India.

Our Indian Government also encouraging generic drugs by establishing Jan Aushadhi stores which procure essential low-priced generic drugs on demand from public-sector drug companies and made them available to general public at an affordable price [23]. But in the present study only 55.9% participants know about "Jan Aushadhi" campaign, launched by Indian Government. In the present study few knowledge gaps were identified. Only 34.2% participants know that generic drugs marketed after expiry of innovator drug's patent. About half of the participants have knowledge about all generics available in the market (57.43%).

Almost all participants (99.5%) in the present study opined that National level generics online reference should be made available. Updated information regarding the generic drugs (as given by US Food and Drug Administration in its Orange Book which provides information of approved drugs with therapeutic equivalence on a monthly basis) will serves as public information and eventually enhance prescription of generic drugs [24]. In India under Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, our Indian Government released price list of available generic drugs which

contains 699 drugs and drug combinations25. In the present study 96.5% participants were of the opinion that there should be a generic store in each hospital (96.5%).

Half of the participants (51.5%) do not know about risk of substituting a brand drug with a generic drug for drugs with low therapeutic index. As far as practices are concerned in the present study 77.7% said that they will prescribe generics to themselves & to their relatives, 81.7% said they will prescribe generics to their patients but only 26.7% said they will prescribe generics in all diseases. Only 34.2% of participants said they read articles on safety and efficacy of generics v/s brand drugs.

In May 2016, the Drugs Technical Advisory Board of India considered amending Rule 65 (11A) of the Drugs and Cosmetics Act, 1940, so that pharmacists can dispense generic medicines and/or equivalent brands against prescriptions in brand names [26]. In the present study 74.3% participants said that they will allow generic drug substitution in place of branded drugs in their prescription by pharmacist. In the present study 86.1% participants said that Patient demand or financial status influence them in prescribing generics, while only 31.2% said medical representatives or pharmacy people influence their prescription. The limitation of this study was importance of generic drugs was not adequately emphasized beyond 2nd MBBS pharmacology curriculum which may affect results of this study, moreover it was conducted in online mode by distributing Google forms in What's App groups and the participants were allowed to fill them in their leisure time which may affect the results of the study.

Conclusion

Poor knowledge of the principles for the entry of generic drugs in to the market results in negative attitudes 27. Knowledge gaps about generic drugs could be eliminated by conducting continuing medical education Programs.

Quality assurance of both brand and generic drugs should be continued after approval through post-marketing surveillance and efficient Pharmaco vigilance program. All these factors may definitely influence the practitioners to improve the generic drugs prescription.

References:

1. Dunne S, Shannon B, Dunne C, Cullen W. A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. BMC Pharmacol Toxicol. 2013; 14:1.
2. Generic Drug Facts. Fda.gov. 2018. Available from: https://www. fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm16799 .
3. King DR, Kanavos P. Encouraging the use of generic medicines: implications for transition economics. Croat Med J. 2002; 43(4):462-9
4. Food and Drug Administration. January 12, 2010. Retrieved 2010-02-03.35 U.S.C. § 154(a) (2).
5. Swain S, Dey A, Patra CN, Bhanoji Rao ME. Pharmaregulations for generic drug products in India and US: Case studies and future prospectives. Pharmaceut Reg Affairs. 2014; 3:2.
6. Aalto-Setälä V., The impact of generic substitution on price competition in Finland, Eur J Health Econ., 2008, 9, 185-191.
7. Savings from Generic Drugs Purchased at Retail Pharmacies". Food and Drug Administration. April 2004. Archived from the original on 2008-02-23. Retrieved 2008-07-11.
8. King DR, Kanavos P. Encouraging the use of generic medicines: implications for transition economies. Croat Med J. 2002; 43:462-9.
9. Jan Aushadhi. An initiative of department of pharmaceuticals, government of India. Available at janaushadhi.gov.in/aushadhi_1.htm. Accessed 2 March 2013.
10. Direction under 33P - central drugs standard control organization. Annexure A. 2012 Available at www.cdsco.nic.in direction 20under 2033P.pdf. Accessed 12 October 2024.
11. The Hans India. 2017. Available from: http://www.thehansindia.com/ posts/index/Civil-Services/2017-05-09/An-analysisof-generic-medicines-in-India/298834 . An analysis of generic medicines in India
12. 12 Andersson K., Sonesson C., Petzold M., Carlsten A., Lönnroth K., What are the obstacles to generic substitution? An assessment of the behaviour of prescribers, patients and pharmacies during the first year of generic substitution in Sweden, Pharmaco epidemiol Drug Saf., 2005; 14: 341-348
13. Himmel W., Simmenroth-Nayda A., Niebling W., Ledig T., Jansen R.D., Kochen M.M., et al., What doprimary care patients think about generic drugs? Int J Clin Pharmacol Ther., 2005, 43, 472
14. Jyoti Ramchandra Patil, Swapnil Chudaman Jaykare, at al; Awareness about generic drug prescription amongst practitioners: a knowledge attitude practice survey at rural set up, International Journal of Basic & Clinical Pharmacology | May-June 2016 | Vol 5 | Issue 3 Page 708.

15. Gupta SK, Nayak RP, Vidyarthi SK. A study on the knowledge, attitude and practice of generic medicines among the doctors in a tertiary care teaching hospital in South India. Nation J Physiol Pharm Pharmacol. 2015; 5(1):39-44.
16. Badwaik RT, Chopade SS, Mahajan HM, Honrao R. Prescribers Views on Generic Medicines: A Study on Knowledge, Attitude and Practice. J Cont Med A Dent. 2015; 3(2):27-32.
17. Dunne S, Shannon B, Dunne C, Cullen W. A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. BMC Pharmacol Toxicol. 2013; 14:1.
18. Davit BM, Nwakama PE, Buehler GJ, Conner DP, Haidar SH, Patel DT, et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009; 43:1583–97.
19. Amit G, Rosen A, Wagshal AB, Bonneh DY, Liss T, Grosbard A, et al. Efficacy of substituting innovator propafenone for its generic formulation in patients with atrial fibrillation. Am J Cardiol. 2004; 93:1558–60.
20. Araszkiewicz AA, Szabert K, Godman B, Wladysiuk M, Barbui C, Haycox A. Generic olanzapine: health authority opportunity or nightmare? Expert Rev Pharmacoecon Outcomes Res. 2008; 8:549–55.
21. Lewek P, Kardas P. Generic drugs: the benefits and risks of making the switch. J Fam Pract. 2010; 59:634–40.
22. Gupta PB. Survey of pharmacists: impact of the generic drug scandal and implications for marketing generic drugs. Health Mark Q. 1996; 13:109–20.
23. Jayaraman K. Troubles beset “Jan Aushadhi” plan to broaden access to generics. Nat Med. 2010; 16:350.
24. Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) [cited 2018 Oct 15]. Available from: https://www.fda.gov/drugs/informationondrugs/ucm129662.htm .
25. http://janaushadhi.gov.in/productlist.aspx
26. An analysis of generic medicines in India. Available from: http://www.thehansindia.com/posts/index/Civil-Services/2017-05-09/An-analysisof-generic-medicines-in-India/298834
27. Banahan B.F., III, Kolassa E.M., A physician survey on generic drugs and substitution of critical dose medications, Arch Intern Med., 1997, 157, 2080-2088.