



JAN AUSHADHI STORES IN INDIA AND QUALITY OF MEDICINES THEREIN

SINGHAL G.L., KOTWANI ANITA* AND NANDA ARUN

Faculty of Pharm. Sciences, M.D. University, Rohtak, Haryana, India, Department of Pharmacology, V. P. Chest Institute University of Delhi, 110007, India. Email: an_mdu@rediffmail.com

Received: 02 Nov 2010, Revised and Accepted: 05 Dec 2010

ABSTRACT

Generic medicines are an affordable alternative to the costlier, patented, branded medicines. However, vast majority of Indian population still has to spend "out of pocket" on costlier, branded medicines. Various surveys in India have highlighted the problem of availability and supply of cheaper generics in Indian market. Recently, Government of India has initiated the scheme of "Jan Aushadhi Stores", planned in each district in the country, to provide for cheaper generic medicines. However, several surveys have focused on poor quality image of generics, both in the mindsets of prescribers, as well as patients. This study is one of the first such studies, which compares the quality of four commonly used drugs -- Alprazolam, Cetrizine, Ciprofloxacin, Fluoxetine, available as generics from "Jan Aushadhi Stores", with that of the respective leading brands, viz., Restyl, Alerid, Ciprobid and Fludac, from the market. These medicines were tested as per the Indian pharmacopoeial guidelines. Results indicate all the four pairs of generics vs. popular branded medicines pass the relevant pharmacopoeial tests, thereby underlining that generics are of as good quality as branded medicines. The study highlights the importance of spreading awareness on quality of generics, amongst the prescribers and the public as well.

Keywords: Generics, Branded Medicines, Alprazolam, Cetrizine, Ciprofloxacin, Fluoxetine.

INTRODUCTION

Despite vast improvement in government's healthcare spending over the last 25 years, there has been no respite on steadily rising medical costs in the country. Cost of medicines constitutes a large percentage of the total medical costs of an individual. As over 95% of the Indian population is not covered by medical insurance such medical expenditure continues to haunt the common man. Spending on medicines now account for up to 80% of total healthcare expenditure. Lack of appropriate price control regulations on medicines in the country further exaggerate the problem.

Currently, fast moving branded medicines are manufactured by MNCs or large Indian companies. The branded medicines are usually expensive as they are strongly promoted through doctors and chemists and such promotional costs add to their retail prices, i.e., Maximum Retail Price (MRPs). The practice of bribing doctors by pharmaceutical companies to create more and more prescriptions is not recent in the country as well as world over. The unethical promotional practices being adopted by the companies make the essential medicines unaffordable to common man.¹

The public sector in the country procures medicines most often as unbranded generics with international nonproprietary name (INN) labeling. These medicines are typically less expensive than brand name medicines and contain the same active ingredient as the original brand name product.² Although generic medicines are an affordable alternative to the costlier patented brand name medicine³ but their poor availability in the public as well as private facilities and exorbitant printed MRPs makes them practically unaffordable.⁴

Medicine surveys have revealed very poor availability of essential medicines in public sector hospitals.^{5,6} In the year 2004-2005, medicine surveys carried out in six Indian states using a standardized World Health Organization/ Health Action International (WHO/HAI) methodology revealed a median availability of a basket of essential medicines to be 0-30% in the public sector outlets.⁵ Therefore, low income patients are forced to buy more expensive medicines from private sector or simply go without treatment. As per 2006 World Bank Reports, 34.7% of Indian population earns less than US\$ 1 per day⁷ and majority of them works in unorganized sector, with an average salary of below \$0.5 per day. Spending on medicines is thus, beyond the reach of sizeable Indian population.⁸

India is well known for its prolific medicine industry and offers low cost quality generic medicines to more than two hundred countries in the world. Every third tablet consumed worldwide is manufactured in India. At home, however, India faces the challenge of equal access to affordable and quality essential medicines for its own population.⁵ Despite exponential growth in the pharmaceutical sector, availability and affordability of essential medicines continues to be an important issue for the healthcare providers in India.

Quality aspects of the medicines are regulated by the Drugs and Cosmetics Act, 1940 and Rules 1945, a central legislation passed by the Indian parliament while the pricing and availability of medicines is governed by Drug Price Control Order 1995 (DPCO). With a view to ensure effective implementation of the provisions enshrined under DPCO, 1995, the Government of India constituted a body of experts known as 'National Pharmaceutical Pricing Authority' (NPPA) in the year 1997, which is presently working under the Department of Pharmaceuticals (DoP) in the Ministry of Chemicals and Fertilizers. This department has been entrusted the responsibilities of drug policy, medicine price control, monitoring of drug prices and related affairs.⁹

With a view to make medicines affordable to a common man, the Department of Pharmaceuticals, Government of India, had recently launched the 'Jan Aushadhi Campaign', in April, 2008, to provide quality generic medicines at lower prices than their counterpart branded ones available in the market. The Department of Pharmaceuticals has opened the public generic drug store campaign in cooperation with various state governments that provided space free of charge on the premises of public hospitals. The Red Cross Society and a few other NGOs run these drug stores and make available quality generic medicines at reasonable margins (18-26 per cent). First such Jan Aushadhi generic drug store was opened in the public sector civil hospital at Amritsar, Punjab in November 2008 and followed by second such store in January 2009 at Shastri Bhawan, New Delhi. More such stores have been opened in the states of Punjab, Haryana, Uttarakhand, Rajasthan, Andhra Pradesh, Orissa, and Delhi. The government has proposed that each of the 660 districts in India will have at least one Jan Aushadhi store to cater the medical need of poor patients.

These stores sell generic medicines (230 different kinds of formulations are presently available) manufactured by five central public sector drug manufacturing units including antibiotics, antipyretics, analgesics, anti-inflammatory, anti-histaminic and

fixed dose combinations formulations at affordable prices.¹⁰ The department could open only 55 Jan Aushadhi stores till March 2010 against the target of 276¹¹ including 20 in the state of Punjab alone. Medicines at lower printed M.R.P. are available to

the patients at highly subsidized rates. The comparison between the prices of medicines available at Jan Aushadhi store and their corresponding market rates of few commonly used medicines are given in Table 1.¹²

Table 1: The comparative price structure of medicines available at 24x7 Jan aushadhi stores and average market prices

S. No.	Name of medicine	Strength	Pack	Jan Aushadhi Price (Rs.)	Average market price (Rs.)
1.	Ciprofloxacin tablet	250 mg	10	11.10	55.00
2.	Ciprofloxacin tablet	500 mg	10	21.50	97.00
3.	Diclofenac tablet	100mg	10	3.35	36.70
4.	Cetirizine tablet	10mg	10	2.75	20.00
5.	Paracetamol tablet	500 mg	10	2.45	10.00
6.	Nimesulide tablet	100 mg	10	2.70	25.00

In spite of the fact that these stores are being established by the Government of India in the larger public interest, reports from a few of these stores suggest that sales are minimal.^{13, 14} Patients appear to be reluctant to purchase generic medicines from such stores on the premises of public facilities because of their apprehensions about the quality of medicines. Even the doctors as well as pharmacists are not exception to such misconception.¹⁵

Although all the five central public sector manufacturing units (CPSU) which supply medicines to these Jan Aushadhi stores are good manufacturing practices (GMP) compliant and medicines are quality tested before their release for sale, yet the quality concerns in the mind of patients as well as physicians is an important issue which needs to be addressed on priority to achieve success of the campaign. Mass education and awareness programs on generics and their quality may help to instill confidence among the patients as well as healthcare providers. Further there is immediate need to carryout comparative quality evaluation studies on generics available at such stores and their equivalent counterpart branded medicines sold in the market. The results of such studies should be published in scientific journals, daily newspapers and be given wide publicity. There is urgent need for advocacy and awareness programs about lower priced generic medicines-their quality and therapeutic equivalence to branded medicines.

The government has, until now, opened these stores in cities rather than in villages and small towns where availability and affordability of medicines is a bigger challenge. The list of medicines available at such store is another bottle neck to serve the purposes for which these have been established. The short supply of the medicines is another problem faced by these stores, as the five CPSUs are not able to ensure continuous supply of medicines. In order to ensure uninterrupted supply of generic medicines to these Jan Aushadhi Stores as well as widen the range of drugs available through these stores, recently, the Government of India has decided to procure generic medicines from small and medium enterprises (SMEs) in the pharmaceutical industry.^[32]

MATERIALS AND METHODS

With a view to compare the quality of medicines available at Jan Aushadhi stores with that of their counterpart branded medicines available in private sector, a comparative quality evaluation study was undertaken on four pairs of commonly used branded and Jan Aushadhi medicines. The branded medicines were purchased from the licensed medicine dealers in the private sector while the Jan Aushadhi medicines were procured from M/S Indian Drugs and Pharmaceutical Limited (IDPL) Gurgaon (Haryana), one of the central public sector undertakings catering these generic stores, for carrying out the studies. The medicines chosen were: Alprazolam 0.25 mg tablets, Cetirizine 10 mg tablets, Ciprofloxacin 500 mg tablets and Fluoxetine 20 mg capsules. The sample size comprised 10x10 tablets/capsules of each version (*Branded* and *Jan Aushadhi*). Qualitative as well as quantitative tests were carried out in a government approved drug testing laboratory following the methods prescribed in the Indian Pharmacopoeia, 2007 as per their

standards laid down under the *Drugs and Cosmetics Act 1940 and Rules 1945*.

The following tests were performed:

1. *Identification test*: Identity of the drug molecule was established by performing identification test through instrumental analysis using HPLC (high performance liquid chromatography) or IR (infra-red spectroscopy) as prescribed for each medicine.
2. *Chemical composition test*: The samples were subjected to quantitative analysis using HPLC instrumental analytical method, as prescribed for each medicine.
3. *Uniformity of content test*: To confirm the uniformity of contents in the batch, the sampled dosage units were subjected to "uniformity of content" test wherein assay on 10 units of dosage form were performed individually using instrumental analytical methods. The test for uniformity of content is not applicable to tablets/capsules containing more than 10 mg; it was conducted only for Alprazolam and Cetirizine tablets.
4. *Uniformity of weight*: All 10 units of sampled dosage forms were subjected to the test for 'uniformity of weight' as prescribed under Indian Pharmacopoeia.
5. *Tests for Dissolution*: The samples were subjected to dissolution studies to evaluate their drug release pattern. These studies were performed in the dissolution media specified in the individual monograph of the Indian Pharmacopoeia 2007 on six dosage units and were indicative of the *in vivo* availability of active drug moiety from the dosage form, i.e., tablet or capsule.

RESULTS

Results of comparative evaluation of quality of paired medicines (Jan Aushadhi v/s branded) are given below

1. *Identification test* – All the four 'paired' medicines of *branded* and Jan Aushadhi gave positive identification tests when tested on HPLC or IR establishing their chemical identity (Table 2).
2. *Chemical composition test* – The quantitative analysis conducted using HPLC method showed that each unit of the tested samples was well within the prescribed limits (Table 2).
3. *Uniformity of content* – This test was performed for only two paired medicines, i.e., Alprazolam and Cetirizine tablets. The results indicated that both the versions of medicines were within the prescribed limits (Table 2).
4. *Uniformity of weight* – All the four paired medicines were found complying test of 'uniformity of weight' as per the Indian Pharmacopoeia (Table 2).
5. *Dissolution test* – The dissolution test for all the four 'paired' medicines were found within the permissible limits of the statutory standards (Table 2).

Table 2: The results of comparative analytical evaluation of branded and Jan Aushadhi drug products

S.No	Quality Parameters	Restyl tablets B. No. D-82796 Mfd. by Cipla Ltd.	Alprazolam tablets.P. 0.25 mg B. No. IDAM-09001 Mfd. by IDPL Haridwar	Alerid tablets B. No. D-72641 mfd. By M/S Cipla Ltd	Idicet tablets B. No. IDSR-06 Mfd. by M/S IDPL Haridwar	Ciprobid tablets B. No. ZHH-1552 Mfd. by M/S Zydus Cadila	Ciproral tablets B. No. 5CP-0509 Mfd. By IDPL Gurgaon	Fludac capsules B. No. JK-8039 Mfd. by M/S Cadila Ltd.	Fluoxetine capsules B. No. IDFC-09/02 Mfd. by M/S IDPL Haridwar
1	Identification (by HPLC)	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
2	Uniformity of weight	Av. wt 112.05 mg (limit 103.64-120.45 mg) Complies	Av.wt.118.19 mg (limit 109.32-127.05 mg) Complies	Av. wt. 183.84 mg (limit 169.6-197.16mg) Complies	Av.wt.142.3 mg (limit 131.62-152.97 mg) Complies	Av.wt.744.34 mg (limit 707.12-781.55 mg) Complies	Av.wt.662.04mg (limit 628.93-695.14 mg) Complies	Av.wt.231.94 mg (limit 208.7-255.13 mg) Complies	Av.wt.225.94 mg (limit 203.346-248.534 mg) Complies
3	Assay (by HPLC)	0.2437 mg (limit 0.225-0.275 mg)	0.2531 mg (limit 0.225-0.275 mg)	10.18 mg (limit 9-11mg)	10.185 mg (limit 9-11mg)	495.199mg (limit 450-550 mg)	505 mg (limit450-550 mg)	20.598 mg (limit 18-22 mg)	19.60 mg (limit18-22 mg)
4	Uniformity of content (by HPLC)	0.2287 mg, 0.254 mg, 0.225 mg, 0.256 mg, 0.250 mg, 0.236 mg, 0.231 mg, 0.232 mg, 0.24 mg, (limit 0.225-0.275 mg)	0.241 mg, 0.2425 mg, 0.2349 mg, 0.2346 mg, 0.2509 mg, 0.2729 mg, 0.2621 mg, 0.252 mg, 0.2501 mg, 0.248 mg, (limit 0.225-0.275 mg)	9.85 mg, 9.73 mg, 9.56 mg, 9.74 mg, 9.75 mg, 9.65 mg, 9.66 mg, 9.97 mg, 9.81 mg, 10.01 mg, (limit 9-11 mg)	9.58 mg, 9.45 mg, 09.36 mg, 9.776 mg, 10.009mg, 11.306 mg, 10.131 mg, 10.209 mg, 11.98 mg, 10.408 mg (limit 9-11 mg)	492.35 mg, 485.51 mg, 485.51 mg, 478.67 mg, 485.51 mg, 492.35 mg, (limit not less than 400 mg)	504.9 mg, 490.03mg, 495.4 mg, 504.99 mg, 487.00 mg, 487.00 mg, (limit not less than 400 mg)	18.74 mg, 18.42 mg, 19.07 mg, 18.74 mg, 18.58 mg, 18.91 mg, (limit not less than 16mg)	20.997 mg, 21.808 mg, 20.12 mg, 19.03 mg, 17.23 mg, 18.02 mg, (limit not less than 16 mg)
5	Dissolution (by HPLC)	0.229 mg, 0.234 mg, 0.233 mg, 0.234 mg, 0.234 mg, 0.238 mg (limit not less than 0.2 mg)	0.228 mg, 0.237mg, 0.223 mg, 0.221 mg, 0.230 mg, 0.238 mg (limit not less than 0.2 mg.)	9.44 mg, 9.44 mg, 9.48 mg, 9.35 mg, 9.35 mg, 9.44 mg, (limit not less than 7.5mg)	9.81 mg, 10.03 mg, 10.23 mg, 9.95 mg, 9.93 mg, 9.85 mg, (limit not less than 7.5 mg)	--	--	--	--

DISCUSSION

In a major step towards encouraging the sale of generic medicines in the country, the Government of India has directed doctors at all the Central government hospitals and autonomous institutions to prescribe generic medicines. It is estimated that nearly 50-80 % of people in the country still did not have access to essential medicines and the practice of doctors in promoting branded medicines was one of the main reason for this shortage This is a welcome step and will curb the often observed practice of prescribing specific brands of a medicine with a rider that no substitute should be supplied.¹⁶ The governments of various states like Rajasthan ¹⁷, Haryana and U.T. Chandigarh had already issued such directions and more states to follow in near future.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 states that every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of medicines. The parliamentary committee has also expressed concern over the rampant irrational and useless drug prescription by many of the doctors with ulterior motives

Taking cognizance of the problem of rising price of medicines the parliamentary standing committee on health and family welfare has suggested a series of measures including promoting use of generic medicines to make drugs more affordable and accessible to the common man. The recommendations tabled in Parliament on 4th August 2010 asked the government to give wide publicity to the

generic medicines so that the apprehensions of the general public fuelled and fanned by interested quarters about generics drugs not being of good quality could be dispelled.

Detailed deliberations and arguments on the issue kept the parliamentarians busy throughout the day and commitment of the government to promote use and production of cost effective generic medicines was visible. The report also pointed out that government scheme of running Jan Aushadhi stores to make affordable drugs available to the public was unlikely to make a significant dent in a country of over 110 crore people. The committee urged more proactive intervention by the government to help people procure life saving medicines at affordable prices as the healthcare costs were the second biggest reason for rural indebtedness.¹⁸

There are no published comparative studies on the quality parameters of the Jan Aushadhi medicines vis-à-vis their equivalent counterpart branded one; therefore, we opted to carry out the study to judge the quality of medicines available in Jan Aushadhi generic stores. The study revealed that the medicines which were tested after procuring from Jan Aushadhi sources are of equivalent and comparable quality to their counterpart branded medicines available in the market. All the four paired medicines behaved alike to all the qualitative as well as quantitative tests performed during the said study.

The present study was limited to only four different kinds of medicines and any general conclusion on the basis of the present study would be unfair keeping in view the size of sample, however,

an attempt was made to know about the quality of medicines available at such stores by comparing the quality of some very commonly used medicines. There is dire necessity of expanding the scope of the study to the entire range of medicines available at such generic stores. The results should be published in scientific journals and daily newspapers and be given wide publicity if found comparable and equal.

There is dire necessity of propagating advocacy and awareness program about the lower priced generic medicines- their quality and therapeutic equivalence to branded medicines, to instill confidence in the minds of patients and physicians about the quality and efficacy of such drugs and also to propagate that patient ask their doctors to prescribe medicines carrying the scheme's logo; retailers would have no choice but to stock them.

The Jan Aushadhi stores which are presently limited to the government sector facilities only should be outsourced to expand their scope to the private sector so that its benefits can be availed by the public in large rather than limited public sector only. The list of medicines available in these stores needs immediate expansions to meet the prescription demand. Such stores should be established in towns, villages and remote areas where there is acute problem of essential medicines. By expanding the sphere of such outlets, the use of generic medicines can be increased.

REFERENCES

1. Wazana A. Prescribers and the Pharmaceutical Industry : Is a gift ever just a gift ? JAMA. 2000 Jan 19; 283(3): 373-80.
2. Nightingale S.L. From the food and drug administration. JAMA. 1998 Mar 4; 279(9): 645. (PMID : 9496968)
3. Joncheere K., Rietveld A.H. and Huttin C. Experiences with generics. In: M.N.G. Dukes, F.M. Haaijer-Ruskamp, C.P. Joncheere and A.H. Rietveld (eds.) Drugs and Money, 7th edn. (2002) The Netherlands: Published on behalf of WHO-Europe, IOS Press, 101-10.
4. Singal G.L. and Nanda A. Generics Drugs in India –Whether an Affordable Alternative to Branded Drugs: A Critical Study. The Pharma Review. 2008 Jun; 6 (34): 637-42.
5. Kotwani A., Ewen M., Dey D., Iyer S., Lakshmi P.K., Patel A. et. Al. Prices & availability of common medicines at six sites in India using a standard methodology. Indian J Med Res. 2007 May; 125(5): 645 - 54.
6. Kotwani, A., Gurbani, N., Sharma, S. and Chaudhury, R.R. Insights for Policy makers from a medicine price survey in Rajasthan. Indian J Med Res. 2009 April; 129(4): 451-54.
7. The World Bank. (2009) World development indicators, <http://devdata.worldbank.org/wdi2006/contents/section2.htm> (Accessed Aug 2010)
8. The Hindu Business Line. (2008) Specialized financial institution needed for unorganized sector 20 February (<http://www.thehindubusinessline.com/2008/02/20/stories/2008022052141000.htm>)
9. Department of Pharmaceuticals. (2009) Ministry of chemicals and fertilizers. Government of India, <http://pharmaceuticals.gov.in>.
10. Kotwani A. Will generic drug stores improve access to essential medicines for the poor in India ? J Public Health Policy. 2010 July; 31(2); 178-84.
11. Shankar R. DoP opened only 55 Jan Aushadhi stores till March 2010, target set was 276. Chronicle Pharmabiz. 2010 June 17; vol. 10 (27): 19.
12. Department of Pharmaceuticals. (2009) Comparative Analysis of Jan Aushadhi & Average Branded Market Price, 16 February 2009, <http://janaushadhi.gov.in>,
13. Tribune. (2009) Jan Aushadhi store not in pink of health. 12 July, <http://www.tribuneindia.com/2009/20090712/bathinda.htm>.
14. Seth A. (2009) Generic drugs not on doc's prescription. Ludhiana Tribune. 19 August, <http://www.tribuneindia.com/2009/20090820/ldh1.htm#3>.
15. Singal G.L. and Nanda A. Evaluating General Practitioner's Perceptions and Practices on Generics and Branded Medicines A Pilot Study from the State of Haryana (India). The Pharma Review. 2010 April; 8 (44): 140-44.
16. Chronicle Pharmabiz. Health Min ask docs in govt hospitals to mention generic equivalents in prescriptions. 2010 June 3; vol. 10 (25):2010; 18.
17. Rajasthan government directs prescribers to prescribe medicines by generic names. Indian Health News 2007 Apr. Available at <http://www.medindia.net>
18. Nagarajan R. Cap profits on drugs, says MPs panel, The Times of India, New Delhi. August 9, 2010