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, Cetirizine, Ciprofloxacin, Fluoxetine, available as generics from "Jan Aushadhi Stores", with that of the respective leading brands, viz., Restyl, Alerid, Ciprohik 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, Cetirizine, Ciprofloxacin, Fluoxetine.
fixed dose combinations formulations at affordable prices. The
department could open only 55 Jan Aushadhi stores till March
2010 against the target of 276 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.

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

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

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. 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.

Although all the five central public sector manufacturing units
(CPSUs) 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
carry out 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.

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
tables 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
diffusion 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).
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 reasons 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. The governments of various states like Rajasthan, Haryana and U.T. Chandigarh had already issued such directions and more states are likely to follow in near future.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 state 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 pro-active 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.

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 and comparable quality to their counterpart branded one; therefore, we opted to carry out the 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

18. Nagarajan R. Cap profits on drugs, says MPs panel, The Times of India, New Delhi. August 9, 2010