7. SURVEYS

7.1 COMPARISON OF THE REGULATORY GUIDELINES ON BRANDED/GENERICS IN VARIOUS COUNTRIES, INCLUDING INDIA, AND TO SUGGEST REMEDIAL MEASURES FOR IMPROVEMENTS.

This part of the research work was aimed at comparison of regulatory guidelines on branded / generic drugs in various countries, with specific focus on USA and India. Following salient points could be noted, amongst the regulatory guidelines on branded / generics, in various countries:

1. USA has one of the best policies towards promotion of generics in the world. Hatch – Waxman Act, 1984, has proved to be the milestone in the launch of generics in USA. The US FDA promotes the generics by offering 180 days marketing exclusivity to the first successful Paragraph IV filer. US FDA has formulated strict guidelines for ensuring bioequivalence as well as bio-availability, as the prerequisites for launching a generic in the country. US laws also aims to protect the interests of the innovator, along with those of generic manufacturers, by providing drug-patent linkage. Further, federal regulations also provides for data exclusivity period of five years wherein no generic challenge can appear. A peculiar characteristic of the US market is universal health cover, so that the government agencies (as well as the insurance agencies, for the private insured citizens) insist upon the usage of generics, which are substantially cheaper. Presently, majority of the prescriptions in USA are dispensed as generics, illustrating the impact of the US generic promotion policies. Substitution by the dispensing pharmacist is allowed under the US laws to promote low cost generics. FDA also maintains an up to date list of all approved marketed drug products, popularly known as “Orange Book”, which serves as the primary source for generic equivalency.

2. European Commission has passed regulations to promote use of low cost generics, e.g., generic prescribing, generic substitution, patient co-payment, incentives to physician, pricing and reimbursement (Perry, 2006). Importance of generic medicines can be seen from the fact that in 2006 generic medicines represented three forth of all the new applications finalized under the Mutual Recognized Procedure. The generic market has been successfully developed through financial incentives to physicians and pharmacists and other generic promotion schemes in the United Kingdom. Although generic
substitution is not permitted but more than 65% of the prescriptions are in fact written generically, thus allowing for dispensing of the cheapest product. However, EU provides long data exclusivity period (8 years), during which no generic challenge would be allowed. Compared with US, EU generic promotion policies score lower- no incentive for generic challenge, fees for generic registration, no free price competition, etc.

In Denmark, the use of generics is stimulated through generic substitution, official publicity campaigns to promote the use of generic medicines and non-financial incentives for the physicians and pharmacists. The substitution is mandatory, if the cost effective generic is available. Most of prescriptions in Europe are written in brand name. In countries where INN prescribing is compulsory, only in Portugal are physicians obliged to do so for all the medicines when a generic product is available (Perry, 2006). In Germany, generic penetration is driven largely by generic substitution, reference pricing and the setting of prescribing budgets for the general practitioners, making doctors and consumers price conscious. The Netherlands has implemented a variety of measures including reference pricing, non-financial incentives for healthcare professionals, generic substitution, teaching generic prescribing at universities, and financial incentives for pharmacists who is allowed to retain 33% of the price difference.

3. In Canada, the province use a wide range of policies to encourage the use of generic medicines including generic substitution, which is mandatory in most of the provinces, incentives to the pharmacists and physicians and a reference pricing system. The generics are dispensed to fill about 50 % of all the prescriptions and the sale of generics is on rise at the rate exceeding 10% annually. The Canada’s Patent Act has ‘Bolar Provisions’, as it allows research and development as well as application for regulatory approval of a generic product prior to patent expiry (www.cgpa.com). However, Canada has some roadblocks to generic promotion, i.e., eight year ban on generic competition, and lengthy litigations upon generic approvals.

4. Japan, the second largest pharmaceutical market in the world after USA, is implementing measures to expand the use of generics amongst the people to cut healthcare costs. The government has introduced incentives for prescribing and dispensing generics, as well as measures to allow generic substitution (Saigura, 2006). The National Health Insurance (NHI) drug price revision in April 2010 has included price cuts for long listed drugs or off-patent medicines for which generics are available. The new policy aimed to
overcome what is known as drug lag (the lengthy period required until new drugs launched overseas are approved in Japan) as the foreign companies have been slow to bring new products into Japan because of expensive and cumbersome trials often duplicating the those already carried out in other countries and mandatory price cuts (Pingle, 2010). The government is planning to switch around 30% of its prescription medicines to low cost generics by 2012.

5. Under the Brazilian law it is mandatory for the generics to display the international non proprietary name (INN) on the package, as well as the words ‘Generico’ (generic) inside on a yellow stripe visible for patients as identification mark to distinguish from branded (Luciano, 2009). The legislation provides for interchangeability of reference drug with a generic medicine. Today four of the six largest pharmaceutical companies in the country are Brazilian and all of them are producing generic medicines. Almost 90% of the generic market is dominated by the Brazilian companies. Branded generics are not allowed. Bio-equivalence test and GMP certification of the manufacturing facility is mandatory. Quality of generic medicines is assessed by ANVISA in coordination with INCQS which takes samples of generics and their innovator counterparts from the market and results are published. Further, Brazilian law requires that the prices of generics should be at least 35% lower than the reference drug prices and such prices have to be pre-approved from the Government. Consequently, owing to the market competition, the prices of the generics are about 80% of the price of their counterpart branded medicines (Valente, 2006). The doctors in the public facilities are required to prescribe generic medicines only. Brazil also adopts one of the best policies to promote generics in the world.

6. Indian drug regulations do not specifically define generics, nor do these laws insist upon BA/BE studies for their approval. There exist no generic promotion policies like mandatory generic prescription, provisions for generics substitution, identification mark on generics, lower price of generics etc. Majority of the medicines in India, are sold under a brand (trade) name and are termed as ‘branded medicines’. Generic medicines have been virtually vanished from the Indian market and are being replaced with branded-generics, which are simply generic medicines marketed under a brand name. Many pharmaceutical companies manufacture both the versions of same molecule, i.e., ‘branded’ which they promote and push through doctors and ‘branded-generic’ version, which they expect
retailers to push in to the market. Medicines prices in India are among the lowest in the world still the Indian patients do not have access to ‘cheaper’ generics (Kotwani, 2010). A comparison of medicine prices of medicines in India vis-à-vis other countries is given in Table 5.2.1.1.

Thus, it can be seen that Indian laws do not support the use of generics. Hence, it is recommended that:

- First of all, the Indian laws should specifically define ‘generics’, and provide for BA/BE studies as mandatory provisions for introduction of generics in the market.

- Indian laws should provide for identification of generics in the market, say, by adding a unique identification code for generics (such as G) before the marketed name (whether brand name or INN).

- Quality monitoring program for generics must be made mandatory.

- The Indian FDA should prepare a comprehensive list of bioequivalent drug products, which are interchangeable, along with their price, and regularly update the same, so that the same can be used by any member of the health care team.

- The Indian laws should be amended to allow the generic substitution by dispensing pharmacists.

- It should be mandatory for the Indian pharmaceutical manufacturers to carry out bioequivalent studies, for all generic products manufactured by them, and the government should arrange for publishing the results of such studies, on a regular basis.

- The government should provide tax incentives for generic manufacturers.

- National Pharmaceutical Pricing Authority (NPPA), Government of India should provide for pre-approval of prices of all categories of generic drugs before launch in the market, and should further ensure a lower price for the generics as compared to the price of the counterpart branded / innovator product.
• Government should provide adequate funds for the development, promotion and quality testing of generics, to the potential researchers, in private sector as well as in government sector / educational institutions, etc.

• Stringent deterrent provisions should be provided for those physicians, particularly in the government sector, who are prescribing branded products.

• Generic prescription should be made mandatory for doctors in the public sector and appropriate provisions of incentives for generic prescribing.

• Government should further enlarge the scope of recently launched “Jan Aushadhi Scheme”, by establishing such stores in more numbers, and also by enhancing the stocks of generic medicines in such stores.

7.2 Survey of the Role of Prescribers in Determining the Availability, Price and Popularity of Generics in the State of Haryana.

The Drugs and Cosmetics Act, 1940 and Rules, 1945, do not allow a dispensing pharmacist to substitute prescription of doctor containing Schedule H drug [Rule (65)11-A] in contrast to the policies being practiced in many overseas nations. Thus, the role of prescribers in India becomes all the more important. Further, in India, generic medicines are procured and distributed to the patients in public sector and government doctors are under directions to prescribe medicines by generic names to their patients only in some of the states, i.e. Haryana, Rajasthan, etc: Recently, similar directions have also been issued by the U.T., Administration, Chandigarh, for the doctors to prescribe generic drugs which are available at Jan Aushadhi Store (http://cpaper.hindustantimes.com/default.aspx) as well as by the Union Health Ministry (Shankar, 2010).

Having regard to the facts delineated above, a necessity was felt to undertake a study in extenso on the prescribing patterns and perceptions prevalent amongst the physicians regarding generic vis-à-vis branded medicines, as being at the center piece of the medication use process and are the dominant prescriber in all clinical setting. The need for such a study became must, especially when very few such studies have been conducted, in the past. Further, to the best of our knowledge no such study has ever been done in the country including the State of Haryana. The study was also
considered vital from the viewpoint of the common man and thereby, by way of the study, an effort has been made to assess the prevalence of the misconceptions/myths regarding the quality standards and therapeutic efficacy of generic medicines as against its counterpart (branded medicines) in the minds of the concerned physicians.

In this study, 500 randomly selected general practitioners practicing medicines in the State of Haryana, from public as well as private facilities, were associated, to assess their perceptions about the generic vis-à-vis branded drugs as well as to adjudge their prescribing patterns. The requisite administrative approval for the study was obtained from the University (no financial interests of any pharmaceutical company were involved in this study). Accordingly, a comprehensive questionnaire was prepared and distributed among the general practitioners practicing across the State of Haryana. Contents of the pre-validated questionnaire are given in Table 7.2.1

Pursuant to and in compliance with the aforesaid process, more than 400 such questionnaire form duly filled in by the practitioners, were received and evaluated on the basis of certain guiding parameters.

RESULTS

This study reveals that more than 40 % of the practitioners never prescribed generics to their patients. However, about 60 % of the practitioners were found to have prescribed generics may be because of governmental directions, or to poor patients or on merit, to their patients. Exclusive generic prescribing physicians were as low as only 17.8%. The statistical data of prescription pattern of the practitioners is given in Table 7.2.2.

From the aforesaid study, it is deciphered that in developing countries, like India, perceptions about the quality of generics are essentially a bottleneck to implement generic promotion policies. This finds support from the fact that only 11.6 % of the generic prescribing practitioners, found it comfortable to prescribe them to their family members as well. More than 40 % of the physicians, who never prescribed generics to their patients, did also never used generics for their own/family use depicting their apprehensions about its quality/ therapeutic efficacy. Majority of the physicians opted for branded medicine for own/ family use. These findings are depicted in Figure 7.2.1.
The perceptions about the quality of generics among the practitioners were also evaluated by assessing their knowledge about the quality standards and the statutory quality requirements for generics. Majority of the prescribers expressed their apprehensions about the quality of generics as well as quality standards on generics; which in effect contributed to the popularity of the branded medicines. The total absence of promotions of generics by the pharmaceutical companies and other related agencies, were also found contributing to a greater extent for the promotion of the branded medicines. Quality perceptions among prescribers regarding generic versus branded, are given in Table 7.2.3.

The study further revealed that the government doctors were more patient friendly than those in private sectors. This can be viewed either attributed to Government policies on generics or their concern about the poor, neglected and underprivileged sections of the society. The prescribing patterns of government vis-à-vis private doctors, as was assessed during the study, are given in Table 7.2.4. The adverse reaction experience of prescribers, regarding generics versus branded is given in Table 7.2.5.

Unethical promotional practices by the pharmaceutical companies throughout the world cause obstacles to a larger extent in the generic prescribing. Pharmaceutical industries invest heavily in inducing prescribers to make use of its products, and there is sufficient evidence that prescribers are sensitive to these promotional efforts which often lead to extravagant prescribing (Wazana, 2000). Recently, the Medical Council of India, in order to curb these malpractices, has amended the Code of Conduct vide notification No. MCI-211 (1)-2009 (Ethics)/ 55667, dated December 10, 2009, which includes ‘not accepting any gift or travel facilities from any ‘pharmaceutical company and the healthcare industries’. In gross violations of the ‘Code of Conduct’ doctors are being offered pre-paid cards for purchasing anything from rations to jewellery in varying denominations depending upon prescriptions of a doctor, by certain pharmaceutical companies (Grewal, 2010). Even the regulatory body has directed the Drugs Controller General of India (DCGI) to amend the Drugs and Cosmetics Act and insert a Section banning pharmaceutical companies from sponsoring doctors and undertaking any such activities that is contrary to Medical Council of India’s norms on medical ethics and etiquette. Further request to suspend the licenses of all such companies who promote unethical practices has also been advocated by Medical Council of India (Pandey, 2010).
The unethical practices by the stakeholders can only be eradicated if the provisions of the newly enacted law are accepted by the medical professionals without any demur and reservation. Still further, Union Cabinet’s approval of the ‘Clinical Establishment (Registration & Regulation) Bill’ to bring clinics under one law is indeed a path breaking move and can go a long way in improving quality of health services in India.

A study reported to have been conducted in Medical College, Calcutta, India on the prescribing pattern of the physicians found that generic prescription was as low as 32.6 % (Biswas et al., 2000). Similarly problems were found with generic prescription during a survey conducted in 1990 wherein 56 % of the practitioners reported problems with generic prescription (Tilleyard et al., 1990).

Recently, a cross sectional survey of randomly selected general practitioners in Melbourne (Australia) was carried out to investigate factors affecting generic medicine prescription among general physicians. Thematic content analysis of their interview identified seven major themes, some of them are: Medicine prescribing pattern, knowledge and confidence with generics, drug advertisement and marketing; brand name substitution by pharmacist; strategy to increase generics, etc. The findings show misconceptions about the safety and efficacy of generic medicines and it recommended motivation, education by the interested parties, i.e., government and generic medicine industry (Hassali et al., 2006). 37% of the surveyed doctors expressed doubts about the quality of generics as per a survey published in Brazilian media (Kermani, 2006).

Numerous such studies assessing perceptions and prescription pattern of the physicians have been carried out throughout the world including United States (Bearden et al., 1980; Bower et al., 1987; Shulkin et al., 1992; Banahan 3rd et al., 1997; Barett, 2005) Australia (Hassali et al., 2004), Finland (Heikkila et al., 2007), Malaysia (De Run et al., 2006), Slovenia (Kersnik et al., 2006), France (Paraponaris et al., 2004), Ireland (McGettigan et al., 1997), United Kingdom (Turnbull et al., 1993) and Jamaica (Williams, 2007). The most common opinion held by the physicians from these countries are their concern about the quality of generic drugs in comparison with branded ones and about the switch ability of certain drug classes considered critical to these physicians. There were doubts about whether bioequivalence of a generic was equitable to therapeutic equivalence to innovator medicine. About 33% of the physicians had experienced clinical problems with generic substitutes that they perceived would not have occurred with the
innovator (Williams, 2007). A systematic review of studies conducted in the US, Canada, UK, India, Italy and Denmark has shown that physician’s awareness about cost of therapeutics is poor (Allan et al., 2007).

During another such study perceptions of physicians in a public hospital towards patented and generic medicines were viewed and it was found that the physicians viewed patented medicines as superior in quality, efficacy and safety. Generic medicines were perceived as more affordable, but with lack of quality control and uncertain efficacy. Factors that affect physicians prescribing decisions include their own experience, literatures, patient affordability and hospital policy (De Run et al., 2006).

An Indian survey cited following reasons for prescribing branded products over generics (in descending order):- the reputation of the firm, the availability and ease of remembering the name, the cost and the impact of medical representatives (Bansinath et al., 1984). Yet in another study on assessing consumer’s perceptions about the generic and branded drugs which was conducted in Malaysia the consumer’s perceptions about the acceptability of generics were found quite encouraging as 40% of the consumers were found using generics with the belief that it will work (Thomas et al., 2009). The finding of the study are tabulated in Table 7.2.6

The Indian Drugs and Cosmetics Act 1940 and Rules 1945 provide similar quality standards for both generics as well as branded medicines. Similarly, the Drugs (Price Control) Order 1995, which regulates the availability & pricing of medicines, also do not differentiate between generics and branded medicines. The present study revealed various misconceptions in the minds of practitioners with respect to the regulations on generics. About 50 % of the doctors who never prescribed generics were found to be unaware about the fact that both types of drugs are regulated by the same statute in India. They were found unaware of the fact that both have to comply with same quality standards before their release for sale and distribution in the market. Therefore, appropriate training cum awareness programs on generic drugs for sensitizing & educating the health care providers, are the basic pre-requisites, to generate confidence about the generics.

Quality and therapeutic efficacy has always been of concern in context to generic medicines. This issue dominates the mindsets of physicians resulting into a major hindrance in implementing generic promotion schemes of the government. Experience of
side effects with generics as also less effect and/or even no effects with generics, were also found to have been reported. But, no scientific explanation could be provided in support of such experience. However, the factum of said experience being the result of the prejudicial mindsets of the physicians towards generics cannot be ruled out.

About 85% of the practitioners (who never prescribed generics) were found well aware about their lesser cost, indicating that low cost of generics does not have any bearing on their prescription patterns. The apprehension about the quality & therapeutic efficacy of generics was found to be the bottleneck for their prescription.

In-spite of numerous studies on quality and bio-equivalence of generic medicines indicating their quality at par with branded medicines (Barbara, 2009), the apprehension about their quality and therapeutic efficacy still dominates the prescription pattern of the physicians, as has been revealed during the present study. There were concerns about the bioavailability, adverse reactions to generics in a study conducted in Australia (Scuderi, 2002). Studies in USA have shown that up to 64% of the medical practitioner surveyed did not understand the concept of bioequivalence criteria used by the FDA to test a generic medicine versus the branded or the originator (Banahan 3rd et al., 1997). The apprehensions of the physicians about the overall quality and reliability of generic medicines was found dominating factor in governing their prescription pattern (Hassali et al., 2010).

Therefore, educating health professionals, especially medical practitioners, pharmacists & nurses, with regards to quality and bioequivalence of generic products compared with the branded products is an important aspect of increasing their confidence in prescribing or promoting generic medicines.

LIMITATIONS OF THE STUDY:-

The present study was aimed at evaluating perceptions of physicians regarding generic medicines. The study covered 500 doctors from the State of Haryana, which could have been expanded by involving more practitioners especially from multi-speciality/corporate hospitals. Practitioners other than those registered under Indian Medical Council Act 1956, practicing allopathic medicines were not covered in the study. The scope of study was limited to practitioners only; other stakeholders (such as pharmacist) were not included in the study.
RESULTS OF THE STUDY

This survey yielded the following results:

1. The trend of generic prescriptions among the government prescribers was found better than the private practitioners, indicating the contribution of the government to promote generics.

2. The general awareness regarding the quality and therapeutic efficacy of generics was found lacking among the practitioners, as majority of the prescribers were found doubting the therapeutic efficacy as well as quality of generics.

3. The practitioner who prescribe generics to their patients, were found opting for branded medicines for their own family. This indicated their reservations / doubts regarding the efficacy / quality of generics.

4. Majority of the practitioners were found prescribing generics to poor patients, keeping the cost factor in mind.

5. Majority of the prescribers know that the generics are less expensive, but still they do not prescribe generics, indicating their misconceptions about the quality and efficacy of generics.

This survey led to the following suggestions / recommendations:

- The government as well as other interested parties (manufacturers / dealers) must take up generic promotional schemes and support general awareness programs on quality and efficacy of generics to instill confidence among the prescribers, who play a key role.

- The generic prescribers should be given incentives; and also, the prescribers who do not prescribe generics need to be given some sort of discouragement / disincentives.

- The government should design appropriate statutory provisions, to ensure that the generics are made available to the public, at a reasonable price only.

7.3 SURVEY OF THE ROLE OF PHARMACISTS IN DETERMINING THE AVAILABILITY, PRICE AND POPULARITY OF GENERICS IN THE STATE OF HARYANA.

Dispensing pharmacists are an important healthcare provider as an integral linkage between the patient and doctor, their role in the healthcare management cannot be overlooked. Dispensing practices and perceptions of pharmacists about generic/branded medicines directly affect the patients, in so far as the availability, choice and safe usage of medicines is concerned. Therefore, a necessity was felt to carry out extensive study for evaluating the dispensing patterns by pharmacists and their views on generics vis-a-vis branded medicines and prescriptions handled by them. The study also became must/important in view of the findings made during an earlier study carried out by the researchers on the prescribing pattern of the physicians, to find out as to whether there exists any relation between the prescription pattern of the prescribers and the dispensing practices adopted by the pharmacists. Efforts were also made to scratch the minds of pharmacists regarding their concepts and understanding about the quality and efficacy of the generics vis-à-vis branded medicines. A pre-validated data collection form was used to collect their views on various parameters depicting their perceptions and practices about generics. Contents of the data collection form are reproduced in Table 7.3.1.

More than 200 such data collection forms were received duly filled from the dispensing pharmacists across the state of Haryana. These were then evaluated on the basis of certain guiding parameters. Based on the observations and evaluations, conclusions were drawn, accessing perceptions and dispensing behavior of the pharmacists.

The study revealed that 100% of the surveyed pharmacies were found stocking and dispensing generic/branded- generic medicines in addition to the popular branded one. However, prescription of generic drugs was found as a major bottleneck in their usage, as majority (55%) of such shops were found receiving only 10% of their total prescriptions as generic prescription, indicating the poor perceptions of generics among the healthcare providers. Branded medicines were found widely available and dispensed actively by the pharmacists.

Similar observations have been reported during a similar study on 40 community pharmacies carried out in Malaysia. The chemist shops located in the vicinity of public
health institution were found receiving about half (50%) of their prescriptions in generic names confirming the results of recent studies carried out in the State of Haryana on the prescription pattern of the physicians. Further, it also speaks about the impact of pro-generic policies of the government.

Generic / branded generic medicines were found being sold by majority of chemists (95%) at highly discounted rates i.e. discount to the tune of 70% of their printed MRP were found being provided by them in the sale of generics or branded generics. No such practices were however, found in case of sale of branded medicines where almost no discount was found being offered by the retailers. The profit margins for sale of generic and branded medicines are given in Table 7.3.2.

In spite of the fact that the profit margins in sale of generic as well as branded - generic were found to be enormous (up to 70%) than the branded drugs(up to 20%) yet, their sale was found negligible as compared to branded drugs, which further confirm the popularity of branded drug. The perceptions about the quality and quality standards of generic medicines were found better among the dispensing pharmacists as depicted in Figure 7.3.1 and 7.3.2.

In a study on pharmacist’s view on generic medicines carried out in United States, Europe and Asia during the period from 1980 to September 2007, pharmacists’ views and behavior towards generic medicines utilization were found affected by economic considerations, quality and bio-equivalency of generic medicines, although in general they were positively inclined towards generic medication use (Al-Gedadi et al., 2008). Dispensing pharmacists were found offering discounts up to the tune of 70 percent on sale of the cost effective generic medicines to the advantage of customer yet their sales were meager. Obviously, the prescription pattern of the doctors was found driving quantum of their dispensing. The generic dispensing was more than 50% in the shops situated near public facilities. Although, the patient can save up to 70% by consuming generics but he has to abide by the doctor’s prescription and cannot substitute it for generic at will. Both patient as well as the pharmacist appears to be helpless in the present statutory scenario.

During a survey in Australia community pharmacist’s perceptions and practices of generic substitution, majority of pharmacists were found supportive of generic substitution. Most pharmacists (93.7%) were willing to substitute generic for brand name
medicines wherever permitted (Ping, 2010). The Australian Government implemented
generic substitution policy in 1994 allowing pharmacists to substitute generic medicines
for same brand name medicines unless the physician disallow it or the patient decline the
replacement (McManus et al., 2001., Lofgren, 2004).

Another study showed that generic substitution by pharmacist was driven by profit
and concerns about increase in PBS expenditure (Hassali et. al., 2005). The pharmacists
were willing to offer substitution as they viewed generic medicines as being safe and
effective in most of the situations (Hassali et al., 2005).

Branded drugs were found widely available and actively dispensed by the
pharmacist during a pilot study carried out in Malaysia (Zaheer et al., 2008). Majority of
the dispensing pharmacists were found aware about the regulatory requirement for the
generics and their perceptions about the quality of generics were supportive.

CONCLUSIONS:

- Most of the pharmacists were found dispensing branded drugs to the patients in
  compliance to the prescriptions being received by them.

- The prescription patterns of the physicians were found having direct bearing on the
dispensing behavior of the pharmacists. Their stock of generic medicines was
found negligible as compared to that of branded drugs. Exclusive sale of branded
medicines at some places indicated impact of brand promotion efforts of
pharmaceutical companies.

- The stocks as well as dispensing of generics were found better in chemists shops
located near public health facilities than those located away from public health
facilities, indicating impact of generic prescription by government doctors.

- None of the pharmacists opted for generic substitution in-spite of its lower cost, as
was obvious, in view of the fact that it is an offence under the Indian drugs
regulations.

- Summarily, the dispensing practices were found prescription oriented. The
awareness and confidence level among the pharmacists was found better than the
practitioners regarding the quality and regulatory control on generics.
RECOMMENDATIONS:

1. Necessary amendment be provided in the Drugs and Cosmetics Act 1940 and Rules 1945 to allow generic substitution.

2. The dispensing pharmacists should be given incentives for generic promotions.

7.4 CRITICAL ANALYSIS OF THE "GENERIC PROMOTION SCHEME—JAN AUSHADHI STORES", LAUNCHED BY THE GOVERNMENT OF INDIA.

In April 2008, the Department of Pharmaceuticals (DoP) under the Chairmanship of Minister of Chemicals & Fertilizer, Government of India (responsible for drug policy and pricing) launched a campaign to promote generic drugs by opening exclusive generic drug stores called ‘24x7 Jan Aushadhi Store’ for easy access to quality medicines at affordable prices (Kotwani, 2010). First such generic drug store was opened in the public sector civil hospital at Amritsar, Punjab in November 2008; 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. 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. This is a novel move by the Indian Government to provide cost effective quality medicines to its people, however, the impact of the policy is yet to make grounds.

These stores sell generic medicines (230 different kinds of formulations are presently available) manufactured by five public sector drug manufacturing companies including antibiotics, antipyretics, analgesics, anti-inflammatory, anti-histaminic and fixed dose combinations formulations at affordable prices (Kotwani, 2010). Department of Pharmaceuticals (DoP) could open only 55 Jan Aushadhi Stores till March 2010 against target of 276 (Shankar, 2010) including 20 in the State of Punjab alone. Medicines at lower printed MRP are available to the patients at highly subsidized rates.

Generic medicines manufactured by the public sector manufacturing units are supplied to these stores for their sale and distribution to the consumers. Although all these five CPSU which supply medicines to Jan Aushadhi Stores are GMP compliant and medicines are quality tested before release 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 scheme. Mass education and awareness programs on generics and their quality may help to instill confidence among the stakeholders. 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. The government and other healthcare providers should propagate advocacy and awareness programs about lower priced generic medicines, their quality and therapeutic equivalence to branded medicines.

Further, 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 these PSU’s are not able to provide continuous supply of medicines. Recently, the Government of India 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, has decided to procure generic medicines from small and medium enterprises (SMEs) in the pharmaceutical industry (Vijay, 2010).

This concept of providing generic medicines at lower printed MRP through these Jan Aushadhi Stores was initiated by the Government of India after the commencement of this research project, after we published our first research paper on the affordability of generics in India which for the first time highlighted the fact that although it is general belief that the generics are cheaper alternative to their counterpart branded yet the same is not true in Indian context. We presume that the Jan Aushadhi Scheme launched by the Government of India in November 2008 was a result of our publication which appeared in June 2008 issue of online scientific pharmaceutical journal “The Pharma Review” Hence, it was considered prudent to expand scope of our study by including survey of the price and quality of generics being offered at these stores, with their branded counterparts, available in the market.

The comparison between the prices of some common medicines available at Jan Aushadhi Store and their corresponding market rates of few commonly used medicines are given below in Table 7.4.1 (www.tribuneindia.com) (Chandan, 2009).
Although, these stores are being established by the Government of India keeping in view the larger public interest, reports from a few of these stores suggest that sales are minimal (Seth, 2009). 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.

CONCLUSION

This is a novel campaign launched by the Government of India for ensuring availability and affordability of essential medicines to the masses. Such stores in abundance across towns and villages apart from cities (in public as well as private sector) must be opened with wide list/range of tested and compared quality medicines to achieve the goal. Medicines with lower MRPs printed on their label as compared to their equivalent counterpart available in the market are available in these stores eliminating the chances of malpractices of overcharging at any level. Provisions of incentives to the doctors as well as pharmacists should be made to popularize the scheme. The stores can be outsourced to private organizations to expand its base so that its benefits can reach to maximum people. Further, to build confidence about the quality and efficacy of generics there is a strong need to carry out comparative evaluation studies on generics in these stores, with their counterpart branded ones, and to publicize such results in the public.