9. CONCLUSIONS AND RECOMMENDATIONS

Generic medicines are cheaper alternative to the costly branded medicines, which provide the same medical benefits to the suffering mankind as these are certified to be perfect substitute for the innovator branded product. A generic medicine is identical in dose, strength, route of administration, safety, efficacy, and intended use. It must contain the same active ingredients as the original formulation. These are produced after patent expiry or when a patent has never existed. They are cheaper than the equivalent brand name drug because of much lower marketing and development costs. Further, generic companies do not incur the cost of drug discovery, burden of proving safety and efficacy through clinical trials. Competition subsequent to patent expiry also leads to reduction in the prices of generics. Thus generic versions help the suffering mankind by providing the drug available at affordable prices while retaining the quality.

High costs of medicines have always been a matter of great concern to the health authorities in providing healthcare to the mankind. Efforts are made globally to provide quality medicines at affordable prices to the public at large. The States are switching to the generic medicines at a very fast pace to achieve the goal of affordability of medicines in view of their advantage of being cost effective over innovator drug product. Since, generics are alternative products with same contents and therapeutic action, their comparatively low cost provides additional benefits to the healthcare providers.

Generics are considered better substitute to their innovator counterpart throughout the world. The States are promoting their utilization to contain the escalating healthcare expenditure by adopting various generic promotion schemes like generic prescribing, generic substitution, reference pricing, INN labeling, generic friendly approval process etc. The generic medicine market is undergoing significant change throughout the world in view of the large scale expiry of the patents in years to come. Majority of the overseas countries are going for amendments or revision in their medicine policies to promote generics.

However, several outstanding issues and concerns continue to undermine the patient and healthcare provider’s confidence in generic products. It is a general belief that the generics are potentially inferior to their branded counterpart. In spite of the fact that generics are bioequivalent to their branded counterpart and are produced in similar
facilities as per Good Manufacturing Practices, still it is widely believed and perceived even in the developed world by physicians and patients as inferior in their quality and therapeutic efficacy to the branded products. Marketing practices adopted by the manufacturers of branded products also propagate the belief that generics are of inferior quality.

Keeping in view the above factual position in mind, the present study was undertaken to explore the truth behind these myths/misconceptions. Marketed samples of some generic and their counterpart branded medicines were subjected to quality tests as per their pharmacopoeial standards, including those available at Jan Aushadhi Stores. The comparative evaluation study conclusively disapproved the above myths/misconceptions and strongly substantiated the quality of generic medicines.

So far, not even a single case of death or grievous hurt has been reported to have occurred in any part of the world, subsequent to the use of generics or after substitution of branded with generic medicines. Even there are no reports of toxicity or major side effect associated with the generics intake. In majority of cases generic medicines were found working well and the results were found comparable with their branded counterparts. Barring the apprehensions or the misinformation prevalent about the generics in general, which can be very safely termed as ‘myth’; nothing adverse can be attributed to the use of generics.

India is the third largest producer of medicines in terms of volume and ranks 14th in term of value at over Rupees one lakh crore. It exports to the tune of US$ 8 billion to 200 countries including the US/EU. At home, however, it faces the challenge of equal access to affordable and quality medicines for its own people. Despite exponential growth in the pharmaceutical sector, availability and affordability of essential medicines continues to be an important issue for the healthcare providers in the country. Over 80% of India’s healthcare expenditure is borne by the patient due to lack of insurance cover or any subsidies. Indian drug regulations do not promote generics for ensuring affordability of medicines to the suffering mankind.

The present DPCO as well as the drug policies of the Government of India has failed miserably in achieving their purposes to provide affordable quality medicines to its people. The availability of medicines in the public facilities was found to be very poor
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across the country. Impact of the directions issued by the Central as well as some of the State Governments to its doctors to prescribe generic medicines is yet to be seen. Even the recent launching of Jan Aushadhi Stores campaign to provide cost effective quality medicines to the patients has been proved virtually futile.

From the detailed studies on emerging trends towards generic medicines throughout the world, medicine price surveys, prescription behavior of practicing physicians, dispensing behavior of dispensing pharmacists clubbed with comparative quality evaluation studies of branded-generic _vis-a-vis_ branded drugs available in the market as well as in Jan Aushadhi Stores; following conclusions are drawn:

1) Indian drug laws do not define the term ‘generic drug’ as per the practices found in many overseas countries.

2) Provisions for mandatory BE/BA studies prior to launch of generic medicine in the market do not exist under the Indian statute.

3) There is no mandatory requirement of lower price of generic medicine as compared to its branded counterpart.

4) The Indian drug laws do not advocate generic substitution, which is a criminal offence under the Drugs and Cosmetics Act 1940 and Rules 1945.

5) Generic medicines are not subjected to prior price approval from Government before launch in the market.

6) Generic medicines provide cost effective alternative and are comparable in quality as well as therapeutic efficacy to their branded counterpart, yet these are perceived as inferior quality drugs. Benefits of lower price of generic medicines do not pass on to the consumers in India because of unfair marketing tactics of drug companies.

7) Most of the countries including the United States, UK, Canada, Brazil, etc., are having pro-generic policies and their interest towards generics as low cost quality medicine is apparent. 1984 Act of United States opened flood gates for generics in America. India does not have any such generic promotion regulations so far, despite its being the largest producer of generic medicines in the world. It has just started working on the issue but the impact is yet to be seen.
8) Affordability and availability of medicines is a burning issue throughout the world, especially in poor countries, and India is not an exception.

9) Medicine prices are high especially in private sector, where availability of medicines is satisfactory, while the availability is very poor in public sector.

10) The recent novel concept of 24x7 Jan Aushadhi Stores launched by the Indian Government is also not picking up, although the generic medicines with lower MRP as compared to their equivalent branded counterpart are available at such stores. This scheme needs to be given a strong push up at all levels.

11) The quality of generics as well as those available at Jan Aushadhi Stores and branded medicines was found identical and comparable within the study parameters.

12) The pharmaceutical companies in India manufacture two or more versions (different formulations) of the same drug molecule as per provisions laid down under the Drugs and Cosmetics Act, 1940, and Rules, 1945, without making any compromise with their quality. However, they adopt different strategies to market them. Products with popular brand names are promoted by the companies while the branded-generics with less popular brand name as well as generics are not promoted. There exist exorbitant differences ‘in mark-ups’ for branded and branded generics, which is very unhealthy.

13) Quality of low cost generic medicines and their equivalent costly branded counterpart was found comparable during the comparative quality evaluation studies.

14) Physicians in India were found having misinformation about the quality, therapeutic efficacy and regulatory aspects of generic medicines. Their minds were prejudiced by the unethical promotional strategies of the pharmaceutical companies in total disregards to the larger public interest. The pro-branded perceptions and prescribing behavior of physicians were found based on the unethical promotional propaganda of the brand name companies.
15) Dispensing pharmacists were found dispensing medicines as per the prescription without allowing any substitution. Majority of the prescriptions were found for branded medicines. The stock position and the meager sale of generics further support the trends.

RECOMMENDATIONS

Based on the results of our study on various aspects of branded and generic medicines, we have tailored recommendations for ensuring affordable quality medicines to the general public in the country.

A. REGULATIONS ON MEDICINES IN VARIOUS COUNTRIES

➢ The Indian drugs regulations should provide for the definition of term ‘generic medicine’.

➢ BA/BE study should be made mandatory for the issue of manufacturing approval of generic medicines.

➢ Prior price approval from the Government prior to marketing of generic medicines should be made mandatory.

➢ The government should ensure a lower MRP on generic medicines than its equivalent branded medicine, as per the practice being followed in some countries, such as Brazil.

➢ The Drugs and Cosmetics Rules, 1945, should be amended to provide for mandatory identification mark on generics (to distinguish them from branded medicines).

➢ INN labeling is mandatory under Rule 96 of the Drugs and Cosmetics Rules 1945. Strict enforcement and compliance thereof is needed.

➢ The generic applicant should be asked to submit comparative quality evaluation studies (branded versus generic) and their data before their manufacturing approval.
Conclusions & Recommendations

- The comparative quality data as well as the MRP of branded and generic medicines should be published in print media to instill confidence about generics in the minds of stakeholders.

- The generic manufacturers should be given incentives like tax benefits, rebates in approval fees and approval time.

- Generic substitution should be allowed to the pharmacists.

B. SURVEY OF PHYSICIANS’S PERCEPTIONS

- Unethical and unfair sale promotional efforts by the drug companies should be made a cognizable offence under the Drugs and Cosmetics Act, 1940 and Rules, 1945.

- Generic prescription should be made mandatory in public facilities and private doctors should also be encouraged to prescribe generics to their patients (for example, by providing tax incentives to such practitioners).

- Generic medicines, their quality standards and affordability vis-à-vis branded medicines should be included in curriculum of undergraduate medical students.

- Physicians who practice and promote generics should be given incentives.

- Training programs for physicians on the affordability and quality of generics in comparison to their branded counterparts should be regularly arranged.

C. SURVEY OF PHARMACIST’S PERCEPTIONS

- Drugs and Cosmetics Act, 1940 and Rules, 1945 should be suitably amended to incorporate substitution of branded Schedule II medicines, with their generic equivalent, by the dispensing pharmacist, on patient’s request.

- Incentives need to be given (by the government) to pharmacists who promote generics.

- Essential Medicines List should be prepared and followed throughout the country.

- All procurement in the public facilities should be in generics only.
D. CONCEPT OF 24x7 JAN AUSHADHI STORES

➢ The scope of Jan Aushadhi Stores should be enlarged with wide range of medicines made available in abundant at these stores.

➢ Jan Aushadhi Stores which are presently limited to the government sector should be outsourced to the private sectors, so that their benefits can be availed by the general public throughout the country.

➢ Such store owners operating in smaller cities, towns and villages should be given special incentives, where the availability and affordability of medicines is sparse.

➢ The Government should undertake comparative quality evaluation studies involving Jan Aushadhi medicines and their branded counterpart to exhibit the quality of Jan Aushadhi medicines.

E. PRICING AND AVAILABILITY OF GENERIC MEDICINES IN INDIA

DPCO, 1995 needs immediate amendment with respect to following:-

➢ The list of price controlled/ scheduled bulk drugs (listed under First Schedule of the DPCO, 1995) should be reviewed, enlarged and updated regularly. Obsolete/ outdated medicines like Analgin, Sulphadimidine, Chloroquine, etc., should be removed and new molecules should be brought under the ambit of price control making it a dynamic entity. Extensive price control on medicines is required urgently in view of the escalating ‘out of pocket’ expenses on medicines.

➢ The ‘maximum sale prices’ fixed by the NPPA (of the price controlled bulk drugs) must be subjected to revision every year. The statutory provisions get diluted if the prices fixed are not revised for years together. To quote an example, ceiling price of Ciprofloxacin hydrochloride has not been revised after its fixation in the year 1997.

➢ Labeling of excessive MRP on the scheduled formulations as well as bulk drugs should be made cognizable offence under the DPCO and NPPA should be vested with powers of criminal prosecutions against the offenders in addition to the present powers to recover dues and overcharged amount. Strict enforcement of the
DPCO, 1995, by the regulatory agencies should be ensured. Additional manpower and infra structure exclusively for its proper enforcement be created.

➢ Present practice of free market for the non-scheduled bulk drugs as well as formulations must be abandoned with immediate effect. The NPPA needs to look in to matter.

➢ Prior price approval should be made mandatory for all scheduled and non scheduled bulk drugs as well as formulations based thereon before market authorization / product approval as per practice prevalent in many overseas countries, like Brazil. Such price approvals can be given along with product approval by the State Licensing Authorities. The price of generics should be lower than its branded counterpart.

➢ National formulary for the fixed dose combination (FDC) formulations should be developed with their ceiling prices, to weed out irrational drugs and to encourage rational use of drugs through standard treatment guidelines.

FUTURE SCOPE

This research work is one of the first studies conducted towards exploring the regulations, pricing and quality of generics in India. The study had inherent limitations regarding the number of drugs covered. There is a strong need to continuously conduct such studies, encompassing all medicines in its basket to generate confidence about the quality and therapeutic efficacy of generics in the mind of healthcare providers as well as general public. The scope of the study can be further expanded by incorporating additional parameters like BA/BE studies.