

Chapter – 5

Discussion

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5.0 Introduction

The findings are discussed in relation to the study keeping in focus perspective of stakeholders such as doctors, patients, populations, chemists, pharmaceutical companies, and regulations. The study reflects insightfulness into the subject and understanding of the issues concerning generic medicines which present as uniqueness of the research. The potential contribution of the research outcome to the subject of knowledge, attitude and practice of doctors towards generic medicines are highlighted.

5.1 Discussions

Branded generics dominate the Indian pharmaceutical market. Branded medicines (branded generics / innovators' drug) are promoted to doctors to get their support in prescribing of brands which are high priced compared to generics retailed at Jan Aushadhi (generic drug stores). However, few branded generic medicines are offered to pharmacies at massive discounts making it lucrative for them to push such discounted products at retail or substitute prescriptions. In-house pharmacies of privately managed clinics and hospitals have also found the heavily discounted branded generics attractive.

Discussions are focused on chemists, patients, population, pharmaceutical companies and government policy followed by medical practitioners so as to have a holistic view concerning generic medicines paving the way for further research and development of marketing strategies specially by the pharmaceutical companies who are the source of

supplies of medicines be it in brand name or generic name and the government for development / amendment of policies.

Holistic approach

As has been highlighted, holistic approach is required encompassing doctors, patients, population, chemists, pharmaceutical companies and government policy concerning prescription of generic medicines. Several interesting aspects have been brought about from review of literature, research, discussions with doctors, chemists, patients, pharmaceutical companies, medical association with regards to generic medicines which are highlighted below:

5.1.1 Patients / Population

Knowledge

Generic drug knowledge correlated highly with the preference for buying generic medicines. Knowledge about generic drugs or positive perception of them increases the likelihood of purchasing them.

Acceptance with recommendation

Decision for acceptance of generic medicines is based on learning about generic medicines from healthcare professionals. One reason for not much use of generic medicines is due to the doctors' practice in recommending medicines in brand names.

Demographics

Inverse correlation has been seen between income and acceptance of generic medicines. High income earners perceive generics as less effective. Low health literacy also contributes to low acceptance of generic medicines.

Women, older adults, less educated, and those with a high net worth individuals displayed lower preference for generic medicines are women,

Severity of illness

People suffering from chronic or serious conditions were less likely to take generics.

Price - quality perception

Low price generics are perceived less effective

Experience with medicines

Satisfaction with previously used medicines is restricting acceptance of generic alternatives

In a study in Finland, it was found satisfaction with medicines used previously is the most important reason for rejecting substitution (Heikkila et al., 2007)

Company reputation

Consumers have been found hesitant in using medicines produced by unknown manufacturers.

5.1.2 Government Policy (*Bioequivalence / Therapeutically equivalence*)

Bioequivalence is an ultimate test considered as “gold standard” that ensures efficacy of generic drug at par with an innovator drug by comparing bioequivalence or bioavailability of a generic drug with an innovator i.e. the availability of a drug and its rate in bloodstream. The bioequivalence of an innovator drug is established at the time of clinical trials.

The Indian market is full of branded generics and generics which may have never been tested for bioequivalence. In its 2016 meeting, the DTAB (Drugs Technical Advisory Board) had agreed to give a three-year window for all existing drugs to submit their bioequivalence data but that policy decision never got translated into the law.

5.1.3 Packaging

The government of India has specified that the generic name of the medicine should be 2 font size higher than brand name. With the legacy of prevalent concept of branded generics over the decades, along with the innovators’ brand, generics are available with brand name. For a common man it is not possible to differentiate between an innovator brand and a branded generic. The innovators’ brand and branded generics are mostly priced the same if the product falls under schedule 2 of drug pricing policy. Some of the branded generics from regional players are offered to pharmacies at heavy discounts who push or substitute prescriptions at the retail counter.

Medicines in generic names alone (without the brand names) are available at Jan Aushadhi stores which is an initiative of Government of India. Apart from no brand name mentioned on the packs/labels, there is no visible differentiator which can easily

identify the generics other than buying from Jan Aushadhi stores whose presence and variety of products by far is unmatched with the presence of privately run chemist shops.

5.1.4 Price

A marked difference in prices between brand/branded generics and generics is observed as can be seen in Table 1 (chapter 1), whereas products under certain category are priced the same be it an innovator product post patent expiry or branded generic. However, in some branded generics, variation in prices can be seen. Few branded generics are being offered at huge discounts to the pharmacies who push them as generics. *The fine line separating companies that promote branded generics to doctors and the companies that do not promote products to doctors but allow high margins to chemists is missing because of which the price benefit is not being passed on to consumers.*

5.1.5 Pharmacists / Chemists

The chemists / pharmacists in India have played a constructive role in making medicines available across pan India. Unlike western countries, the business in India is highly fragmented mostly run as standalone entities whose motif is driven by running a profitable business.

Following are the key highlights from the study:

- i. Pharmacists are considered as an important source for giving advice or recommending generics to patients.

- ii. Negative perception about generic medicines is being held by a majority of pharmacists who perceive generic medicines low in quality, hence less safe and less effective.
- iii. Some of the companies offering branded generics are giving an opportunity to chemists in making more money due to huge discounts being offered by them as a result the pharmacists tend to push or substitute those products.
- iv. In India, the price difference for generics to patient was not high but profit margins to chemists were very high for branded generics.

5.1.6 Pharmaceutical companies

The major highlights of the research study with regards to companies engaged in manufacturing, distribution & promotion of medicines are:

- i. The promotional brand management strategy adopted by pharmaceutical companies enables them to differentiate products from others.
- ii. The promotional activities of pharmaceutical companies influence 20% of doctors with their prescription.
- iii. Brand name of medicines influence only a few percentage (13%) of medical practitioners.
- iv. Availability of medicines has huge influence on large number of doctors (93%) who tend to prescribe medicines which the patient may access easily.
- v. Reputation of a local company or a company operating internationally is favored by majority of doctors for prescribing their products due to perceived higher level of safety.

- vi. Medicines at Jan Aushadhi stores are not promoted to doctors.
- vii. A few branded generics are being offered at huge discounts to chemists and pharmacies of mostly privately run primary and secondary care healthcare centers.

Following are the key discussions of the study with regards to influence of knowledge, attitude & practice of generic drugs amongst medical practitioners:

5.1.7 Medical Practitioners

Knowledge of generic medicines amongst medical practitioners

Knowledge of generic medicines in medical practitioners has an influence on generic medicines. Knowledge in areas such as awareness of guidelines given by MCI to prescribe medicines in generic names, generics being same as brands/innovator medicine in composition, dose and indications, and interchangeability of branded/innovator medicines by generics has been found to be adequate. However, concerns remain in areas such as marketing of generics after patent expiry of innovator medicine, therapeutically equivalence, bioequivalence, and limited awareness of Jan-Aushadhi scheme. Not much prescription of generic drugs can be explained by overall insufficient knowledge of generic medicines in medical practitioners.

Attitude towards generic medicines amongst medical practitioners

Negative perception about generic medicines are being held by a majority of doctors who perceive generic medicines low in quality, hence less safe and less effective. 40.8% of the doctors are found to be neutral on effectiveness of medicines at Jan Aushadhi. Majority of them have been found to be holding views in favor of medicines

of multinational companies, company reputation and higher level of safety with branded medicines. 42.8% of physicians believe that drug companies engaged in promotion influence prescription pattern of medical practitioners while 46.3% of physicians have the opposite belief. Overwhelmingly, 83.4% respondents believe that medical practitioners should be educated more about generic drugs and 90.8 % believe that doctors should have more confidence in recommending generic drugs.

Practice amongst medical practitioners influencing prescribing of generic medicines

Majority of doctors did not agree with pharmacies substituting branded medicine with a generic one as they had doubts about quality, efficacious and safety of generic drugs.

Factors favoring prescribing medicines are due to consideration of following factors:

- Consideration of socio-economic status of patients
- Disagreement with incentive for prescribing generic medicines
- Agreement on liberty to patients for choosing generic alternatives
- Unyielding to patients' demands
- Uninfluenced by medical representatives
- Disregard of easy remembrance of brand names

Majority of them have shown unwillingness to prescribe generic medicines due to

- Hesitation in prescribing generics in all diseases
- Wider reach & availability of branded medicines
- Unavailability of published literature detailing efficacy & safety comparison between branded and generic medicines

Majority of them are in disagreement with mandatory prescribing of generics.

Mixed reactions were seen from the literature review and study findings in recommendation, acceptance and usage of generic medicines by doctors, consumers, patients & pharmacists which was due to divergence of views because of several factors such as awareness & opinions, consumers' demographic & socioeconomic background, medicine reimbursement scheme, government policy & regulations, experience with medicines in the past, severity of illness, relations with doctors, marketing promotional strategies of pharmaceutical companies, country development level. However, major increase in display of knowledge and confidence towards generic drugs has been observed over the years, mainly in developed countries.

5.1.8 The contentious issues

If doctors start to prescribe more and more of medicines in generic names will it solve the problem of reducing the cost of medicines to patients in present scenario? How can the negative attitude / perception held by doctors, chemists, patients about safety & efficacy of generics be changed? Marketing strategies adopted by pharmaceutical companies enables them to differentiate their products and has influence on doctors. How generics can be marketed? People do not have knowledge of the subject. How do they know what is being dispensed, is it innovators' drug, branded generic or generic? Chemists are commercially driven. Product having combinations of drugs as a composition poses another challenge in terms of prescribing such products in generic names. There are several questions that touch contentious issues which need to be looked at from different perspectives for which an attempt has been made as illustrated below.

Quality

How attitude / perception towards quality of generic medicines may be addressed specially amongst doctors who are the prescribers of medicines? There are many pharmaceutical companies in India manufacturing and distributing products regionally and nationally. What system need to be put in place that would ensure all the generics are of standard quality providing enough confidence to doctors in prescribing generics? There has been concerns amongst patients, doctors and chemists on quality of generic drugs. If the patients do not get satisfactory relief from illness with the use of generic drugs, doctors run the risk of losing patients and negative publicity. With quality concerns on generics why would doctors prescribe them (generics)? Eventually, will the patients whose responsibility for curing the illness rests on doctors, be benefitted with the dispensation of generic medicines?

Generic drug registration

Perceived differential quality standard between medicines of known & unknown companies may be attributed to regulatory requirements currently followed for generic product registration. Bioequivalence, a gold standard test, is an ultimate test that ensures efficacy of generic drug at par with an innovator drug by comparing bioequivalence or bioavailability of a generic drug with an innovator i.e. the availability of a drug and its rate in bloodstream. The bioequivalence of an innovator drug is established at the time of clinical trials.

India for long followed a regulatory practice which allowed approval of drugs with established bioequivalence studies by CDSCO (The Central Drugs Standard Control

Organization) within 4 years of approval of new drug after which drugs could be approved by state drug authorities without the bioequivalent test. As a practice, companies would apply for issue of manufacturing license for a generic drug after completion of 4 years after the approval of new drug which exempted them for bioequivalence test.

The Indian Drugs and Cosmetics Act Amendment 2017 gave blanket “bio-waiver” to drugs classified as class I & III on the basis of in-vitro studies. The drugs are classified into 4 categories (classes I, II, III, IV) on the basis of solubility and permeability. The practice of “bio-waiver” protocols are not standardized across the world; while one country may give bio-waiver to a drug but another country may require bioequivalence test for the same drug.

The Indian market is full of branded generics and generics which may have never been tested for bioequivalence. In its 2016 meeting, the DTAB had agreed to give a three-year window for all existing drugs to submit their bioequivalence data but that policy decision never got translated into the law.

Patients

Let's look at with the perspective of patients who incur high OOPE. On getting prescription in generic medicines, the next question is from where will the patient have the prescription filled for generic medicines? Presently generic drugs (without any brand name) are available at Jan Aushadhi stores where supplies besides its numbers and spread, availability of range of products and access to such stores have been a

constraint though improving. So, what seems critical is patients' acceptance of generics medicines and generic substitution.

Chemists

Next is the issue of the chemist. As per government directive, the doctors are supposed to write prescription in generic name but it is the chemists who will dispense based on their possible bias - what is available and what is more profitable to them. Let's look at it from the chemists' perspective, chemists keep stocks of wide ranging products of branded medicines. Some of the products though in branded form are being pushed by pharmaceutical companies through chemists who are being offered heavy discounts. Interestingly, heavy discounted products to chemists are not being promoted to doctors and some of the companies have two brands of the same molecule, one being promoted to the doctors and the other being offered at heavy discount to chemists. Why the pharma companies are doing this is not so far clear. This offers chemists much more lucrative proposition to substitute branded medicines with unknown substitutes (another equivalent branded medicines) which are treated as generics. The motive of chemists may often be commercially driven, obviously maximization of profit may take precedence over benefits to patients. In light of current scenario, decision on dispensation of brand will shift from doctors to chemists which may not meet with the objective of the government's directive until policy on pricing of generics/branded generics is addressed.

Low margins to chemists allowed on low priced generics (without any brand name) currently available through Jan Aushadhi stores may not make it a commercially viable business for a chemist considering fixed and variable overheads in running a pharmacy

shop with a qualified pharmacist. Then why would a chemist promote generic medicines?

Another issue concerning dispensation of medicines at chemist shops may be the unavailability of qualified pharmacist at few shops. There have been instances of chemist shops having been sealed or licenses suspended by regulatory authority for being run without a pharmacist. In light of this, will the unregistered person or an unqualified person the so called pharmacist may be available in few chemist shops, will the person be in a position to play his or her role effectively and responsibly attending to patients in the promotion & dispensation of generic medicines?

Pharmaceutical companies

Better communication between healthcare professionals and patients may help in educating patients about generic medicines and its acceptance. But then why doctors should be doing this? If we look at it from doctors' perspective, it is largely believed that possible commercial orientation of some doctors supplemented with preferential promotion of branded medicines by pharma companies involving benefits to doctors is a major hurdle in prescribing generic medicines.

Perspective of pharma companies in the marketing of generics is another area that needs to be looked at. In addition to manufacturing and distribution, brand management strategy and promotion has been an area of focus of many leading companies to obtain the prescription by its brand name. The strategy on brand management enables companies to differentiate products from others. The question arises, how a pharma company can differentiate products in generic names? In other

words, how generics need to be promoted to doctors? Prescription in generic names will be filled by chemists who will like to dispense those products on which they can make more money and not necessarily the generic medicine being promoted of a particular company.

The role of medical representatives have been recognized in developing closer relationships with doctors which influences them in prescribing brands. Apart, the collaborative approach between doctors and pharma companies assist each other in inventing new and improved medicines for the wellbeing of the society. MRs establish communication channel between them. The role of MRs may not be of much worth if doctors were to prescribe generic medicines. What would be the communication channel between doctors and pharma companies for promotion of generic medicines needs to be pondered over?

There are many questions that arise with the directive of the government asking doctors to prescribe generic medicines. Doctors being the key decision makers in prescribing medicines are the ones whose inputs are vital. The study has attempted in developing a deeper understanding of knowledge, attitude and practice towards generic drugs. The insights from the study may be found useful in addressing the issues surrounding low acceptance of generics from different perspectives.