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Mess of Generics: The Ground Realities - Indian Pharmacy Practice

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ABSTRACT

Generic medicines are expected to reduce the financial burden while offering the desired efficacy and safety. Despite India being global leader in generic, common public in India is unable to get the complete combination of benefits in terms of cost and quality (efficacy & safety). N numbers of articles are published and addressed the issue. But Almost all articles on this issue have identified the concern with superficial reasons for the same, which we have mentioned here as VISIBLE REASON (reported reason). We have made an attempt to address the correctable, underlying, factual reasons (mentioned here as GROUND REALITY) responsible for those concerns and reasons themselves. Findings are based on our vast and direct exposure to pharma-sales/hospital pharmacy, industry, community pharmacy and teaching where we observed the ground realities responsible for preventing the common man to get the benefit generic in terms of efficacy, safety and cost.

INTRODUCTION

The evolution of pharmaceutical sector in India may be set into four stages. First stage is the period before the year 1970 in which the Indian market was dominated by foreign companies with little domestic participation. The second stage is the period between 1970 and 1990. During this period several domestic companies started operations. Indian Patent Act 1970 was enacted during this period. 1990-2010 constituted the third stage. During this period the liberalization led Indian components to launch operations in foreign countries. The Patent Act was amended in the year 2005 which led to adoption to product patents in India. During this period India became a major generic drug manufacturing country. After 1970 small pharmaceutical manufacturers got opportunity to sell the molecules whose patent was expired. This gave fuel to huge growth to their turnover and In India major beneficiaries were Cipla, Cadila, Deys, Ranbaxy, Sarabhai, Plethico, Lupin etc. Later in late eighties new and smaller companies also joined the sale of such drugs thru their marketing and sales team. Developed countries providing national health insurance and big institutional buyers' also started buying these economical versions to reduce the huge financial burden compared to prices of brands from Research Company who were having patents. Then the word "GENERIC" came. Subsequent to this Doctors in those countries agreed to prescribe generic name and accepted the same from pharmacy. These generics in developed countries[1-2]:

1. Were supposed to have approval from rigid regulatory bodies like US FDA, As long as generic manufacturers could prove their drugs were bioequivalent to brand-name drugs, meaning they acted similarly in the body, they could get approved. Regulatory bodies have liberty to inspect those plants any time and documentation are also scrutinized seriously by independent agencies.

2. Were sold through organized pharmacies run by accountable and qualified pharmacists. India is a significant player and one of the largest suppliers of generic drugs in international market[3]. More than 50 percent of the global demand for various vaccines is met by the Indian pharmaceutical industry. In addition, the industry also satisfies nearly 40 percent of generic drug demand of US and 25 percent of all medicines imported by UK. Currently, the supply of over 80 percent of the antiretroviral drugs that are being used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) is made by Indian pharmaceutical firms[3].

The pharmaceutical industry in India, unlike the country's chemicals, petrochemicals, oil & gas and mining industries, is one of the most fragmented comprising of well over 10,000 companies out of which today, there are over 2,000 WHO, GMP approved plants. This is testament to the size of the market and country, as well as a pharma ecosystem that has collaborated very well over many years. It is a matter of pride that many of the SMEs of yester years have become large-scale national companies now. Indian firms accounted for 35-40% of the global USFDA 971 approvals in 2018[4].

Issues preventing the benefits by sales of generic medicines and ground realities:

Before we address the issues; let us clarify the FIVE categories of formulations prevailing in pharma. Market:

i) **Patented Brand**: Patented Brands are marketed by Pharma co. who invented the molecule after spending huge money/time/efforts. They normally have huge budget for R&D. Therefore their prices for the buyer are genuinely high.

ii) Generic Brands: Generic Brands are of four types **(ground realities).**

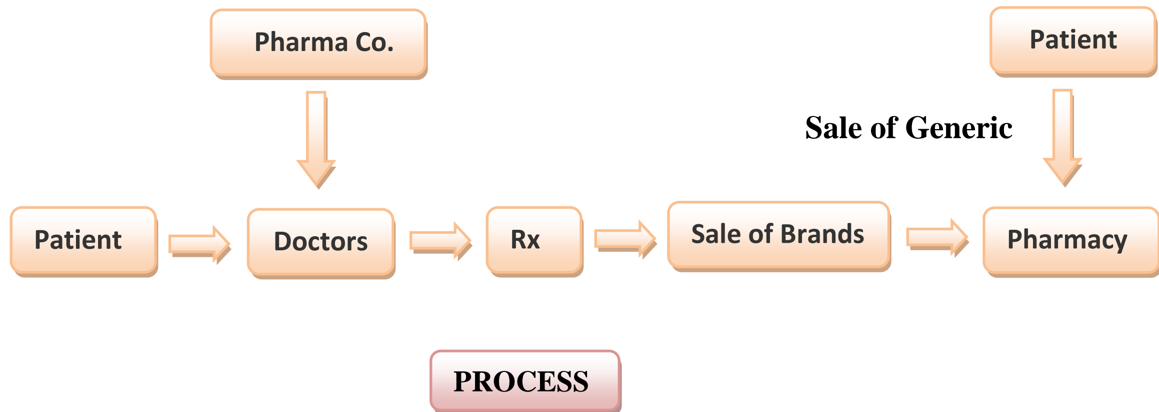
a) Branded Generics (called ethical too): term is used for the brands promoted by pharma. co. who brought bioequivalent version after the expiry of patent of molecule. These are promoted to doctors by medium and large companies thru sales team implementing the marketing strategies designed by product management team. It is assumed that sales of these (ETHICAL??) branded generics are based on ethical scientific services without commission to doctors coupled by request of medical representatives carrying promotion in-put to influence the doctor to prescribe for them. These results in high promotional expenses therefore MRP of these brands are high. Apart from this, they are major source of revenue for the company. Although Indian companies hardly spend on R&D.

b) Propaganda Brands: These are mostly promoted by small companies where doctors receive commission on sales in terms of money or sponsorships. MRP on these brands is highest possible; because these brands do not have fear of competition and substitution;

c) Branded generics (Chemist): These are the generics directly promoted to pharmacies at very low cost and high MRP (50-500%). These brands are pushed over the counter against so called

self-medication and on substitution in very small percentage of prescription of ethical generic brand.

d) Generic-Generic: These are mostly bulk pack sold as active ingredient not as brand, sold as bulk quantity against tenders from institutions.



PROCESS

ISSUE #1

Efforts by state agencies to address the issues/challenges:

The Government of India and some states in India have launched schemes or programs that aimto provide quality medicines at affordable prices to the masses all over country through special centers. In this context one is the Pradhan Mantri Bhartiya Jan Aushadhi Pari Yojana Kendra (PMBJPK) another by the Rajasthan Government through the Rajasthan Medical Services Corporation Limited. The PMBJP is a novel project launched by the Government of India through the Department of Pharmaceuticals, Govt. of India. It aims to provide quality medicines at affordable prices to the masses all over country through special centers or Kendra's known as Pradhan Mantri Bhartiya Jan Aushadhi Kendra. The PMBJPK have been set up to provide generic drugs, which are available at lesser prices (low MRP) but are equivalent in quality and efficacy to the expensive branded drugs.

These centers are a great benefit to people, especially the poor who cannot afford expensive treatment using branded medicines. The Bureau of Pharma Public Sector Undertakings of India (BPPI) has been established under the Department of Pharmaceuticals, Govt. of India, with the support of all the Central Public Sector Undertakings (CPSUs) for coordinating procurement,

supply and marketing of generic drugs through the Pradhan Mantri Bhartiya Jan Aushadhi Yojana which will be dispensed by the Kendra as set up under the scheme[10].

The first "Jan Aushadhi Medical Store" was opened on 25 November 2008 at Amritsar in Punjab. In September 2015, the 'Jan Aushadhi Scheme' was revamped, modified and introduced as 'PradhanMantriJanAushadhiYojana'(PMJAY). Again in November 2016, the scheme was renamed as Pradhan Mantri Bhartiya Jan aushadhi Pari Yojana (PMBJP) (A study on generic prescription, 2014).

In the financial year 2016-17, Bureau of Pharma PSUs of India (BPPI) has done Rs. 33.00 Crores sales at MRP and in the subsequent financialyear2017-18, BPPI has doneRs.112.00 Crores sales at MRP till 31.12.2017 and the projected sale shall be more than Rs. 120.00 Crores sales at MRP by end of this financial year, which corresponds to approximately Rs. 600.00 Crores of the branded products[3].

A) Visible Reason (Reported Reason):

a) Number of these centers' is limited and marketing to develop confidence in these centers are almost negligible.

HUMAN

b) People only due to photo of prime minister and name government undertaking are visiting these centers, out of which more than 60% patient do not know that they are getting substitutes. Around 40% visit with demand of economical substitute.

B) Ground Reality:

a) Before launching of such ambitious plan, government did not amend the relevant laws. Ironically in Chapter '8' point 13 c of PCI regulation explains that pharmacist cannot substitute without approval/consent of the Registered Medical Practitioner. The following acts of commission or omission on the part of a registered pharmacist shall constitute professional misconduct rendering him/her liable for disciplinary action:

a. Violation of the regulations framed under the Act.

b. Dispensing medicines without the prescription of the Registered Medical Practitioner which are required to be dispensed on prescription only.

c. Substitution of the prescription without approval/consent of the Registered Medical Practitioner.

Same is mentioned in Drug and cosmetic act in rule 65 11a., which says:

65. Conditions of Licenses: Licenses in Forms 20, 20-A, 20-B, 20-F, 20-G, 21 and 21-B shall be subject to the conditions stated therein and to the following general conditions:

(11) The person dispensing a prescription containing a drug specified in Schedule H and Schedule X shall comply with the following requirements in addition to other requirements of these Rules.

(a) The prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;

(b) If the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals, it must not be dispensed otherwise than in accordance with the directions;

(c) At the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

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(11-A) No person dispensing a prescription containing substances specified in Schedule H or X may supply any other preparation, whether containing the same substances or not in lieu thereof.

At another place, government is launching generic pharmacy where only substitution without consent will take place at other.

b) Under the cover of banner of PMJAY. These centers are selling branded generics from other pharma company (bearing very high MRP) with a greedy motive to earn margins ranging from lucrative 50% to 500%, without regard to the cost impact on the patient. This practice hits at every root of the aim to make medical care affordable to all strata of society. 20-30% Discount offered to patient is merely eyewash and psychological euphoria. This is because:

The formulary is not covering all the molecules approved in Indian market so as to maintain range, nor the items in the existing list or formulary of theirs is in constant supply so these Kendra are compelled to sell such generics, especially for chronic diseases. THANKS to strongly

favorable culture, CORRUPTION has started from the stage of getting affiliation for this scheme to keep eyes closed for above deviations.

c) Because doctors do not support and incomplete range is there patient has to go to regular pharmacies.

ISSUE # 2

Common Indian man cannot afford the brands prescribed by doctors:

A) Visible Reason (Reported Reason):

Brands under patent from original company: Branded ethical generic and propaganda product sale on prescriptions by doctor. Companies on account of promotional expenses and high profiteering print highest possible MRP. Patients have no choice but to pay for the same. Margin for pharmacy on such brands is 20%+ any offer.

B) Ground Reality:

a) Regarding cost: National Pharmaceutical Pricing Authority (NPPA) could not address the issue effectively. As formula adapted to consider the average Price to Retailer (PTR) of 10 leading brands to calculate the ceiling did not yield meaningful reduction as major reduction was for original brand or top three who have limited market share, majority of brands continued the same maximum retail price (MRP).

b) Regarding efficacy and safety, weak legislation and corruption are discussed below under various issues.

ISSUE # 3

Doctors are not prescribing generic name of drug:

The medical community is asked to follow MCI's 2016 notification in which it had amended clause 1.5 of the Indian Medical Council (Professional)-Conduct, Etiquette and Ethics Regulations, 2002, in this regard. It states that every physician should prescribe drugs with their generic names only[3]. Doctors literally gave no ear to this instruction from their highest Body (Powerful?).

A) Visible Reason (Reported Reason):

a) Doctors prescribe propaganda brands for additional earnings.

b) Doctors who don't go for propaganda brands; they do not have faith in non-ethical generic brand pushed by pharmacy.

c) This relates to the fact that prescribing generic drugs by doctors will merely shift the focus of the pharmaceutical industry's unethical drug promotion to the pharmacist, away from the prescriber. This will again result in the spread of unethical pharma business[11]. Patient continues to pay more[3].

d) More than 50% pharmacies run by unqualified pharmacist against the fake consent from registered pharmacist for meager amount. These people may not care for ethics and are profit driven. Doctors feel challenged to leave the fate of their patients in such hands. This apprehension is reasonable as well.

B) Ground Reality:

a) Doctors connect to company emotionally by in person representation by company.

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b) With this doctors' self-esteem is being nourished to maintain ego of being final decision maker.

c) Most of the Pharmacists who run the pharmacy are NOT among meritorious candidates from academics who are likely to have good clinical exposure hence higher belief in ethics and quality. In western and gulf countries where license is granted after two tough exams where pharmacist enjoys high repute with substantial accountability therefore doctors are prescribing generic name. A strict vigil from drug authorities will limit the no. of such unwanted pharmacies, which will help handsome earnings to pharmacist so less corruption.

d) Corporate lobbying: pharmaceutical companies have high dependence for business thru prescription generated for their brands. So they try to maintain status-co to avoid implementation of corrective and meaning full measures.

This approach of pharmaceuticals is logical as if their profitability is adversely affected their survival will be difficult. As such they operate under pressure of cut throat competition being highly fragmented sector.

ISSUE # 4

Patients' Perspective:

A) Visible Reason (Reported Reason):

a) Traditionally Indians treat doctors next to god and do not dare to budge a inch against doctors' advice. Therefore buy whatever brands doctor prescribes.

b) Government and Charitable healthcare sectors, that may provide economical medicines is the last choice under compulsion.

B) Ground Reality:

a) Effective means to educate about suitability of economical generic- generic is not adapted by responsible agencies like Pharma-Clinics run by adequately.

b) Some online pharmacies and private retail chains who are promoting consultation services to provide economical generics are promoting branded generics (for chemist) due to commercial reasons (A BIG EYE WASH). As patients are not getting appreciable savings due to difference of 30-40% discount on already high MRP.

c) Although patients respect pharmacy owners as 'HALF DOCTOR' but hardly ask about substitution with economical brand of good quality.

d) Neither doctors nor social opinion makers support any meaningful instrument for concept of non-branded generics.

ISSUE # 5

Pharmacist Perspective:

Ultimately execution of delivery of medicines lies with pharmacists being a legal, professional and commercial part of the chain.

A) Visible Reason (Reported Reason):

a) Pharmacy practice is in very primitive stage, which if operates efficiently can help better healthcare.

b) More than 50% pharmacies run without pharmacist.

c) Remaining 50 % pharmacies are not owned by competent pharmacist.

d) Curriculum does not cover pharmacy practice as serious career option.

B) Ground Reality:

a) Most generic drugs sold in the Indian retail pharmaceutical stores are branded-generics(for chemist), which come with premium MRP compared to non-branded generics; efficacy and safety of which can be comparable, subject to strengthening of system. Therefore these branded generics are pushed by retailer as OTC or as substitution on small percentage of prescription with a greedy motive to earn margins ranging from lucrative 50% to 500%, without regard to the cost impact on the patient. This practice hits adversely at the very root of the aim to make medical care affordable to all strata of society. 20-30% Discount offered to patient is merely eyewash and psychological euphoria.

HUMAN

b) In India pharmacist heavily count on patronage or favor of doctors who are practicing nearby pharmacy. Doctors many a times speak negative about pharmacy making patient apprehensive of visiting such pharmacies. Therefore even if patient wants pharmacist is reluctant to provide substitutes.

c) Factors adversely affects the pharmacies are:

- The cut throat competition among pharmacy is due to discount-war, perpetually increasing number of pharmacies,
- Corrupt practice by unqualified pharmacy owners in competition and high operating expenses.

d) Low salaries or complex business environment does not attract meritorious pharmacist to this profession.

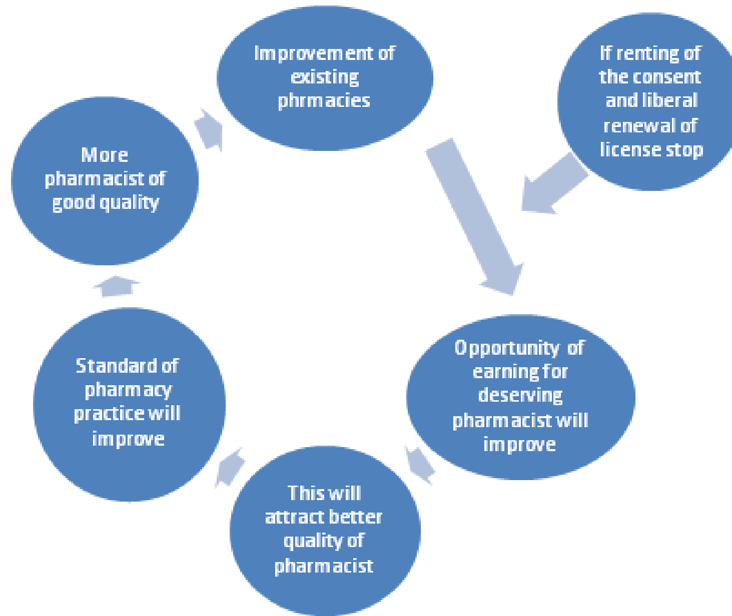

Diagram shows Low salaries/complex business environment does not attract meritorious Pharmacist to this profession.

Examples of improvement in professions (Qualification does count)

S No.	Work	Earlier Practiced By	Qualification Now	Impact
1.	Designing House	Civil Engineers	Architects	Better planning With Creativity
2.	Income Tax Return	Lawyers/ Accountants	LLB/ Charted Accountant	Better Financial Results & Ethics
3.	Treatment	RMP	MBBS +	Rational & Better Therapy, Safety
4.	Rehabilitation	None	Physiotherapists	Early Recovery With Min. Deformity

ISSUE # 6

Policy Making:

A) Visible Reason (Reported Reason):

a) Weak Legislation related to pharmacy: right from education to manufacturing to research to practice, laws appears to more of an assay. Rules lack objectivity and specificity. Due to lack of

transparency in the licensing procedures of Drugs, it has resulted in the increased supply of low quality, spurious and substandard drugs. With reference to a WHO study, Mashelkar Committee has declared the data that nearly 30% drugs in Indian market are spurious, substandard, counterfeit drugs. Although there are various bodies present but their actual implementation to maintain the quality of drugs is not sufficient as government is itself coming up with data like there are 8-10% substandard drugs and 0.3 to 0.5% spurious drugs in the Indian market[4-19].

b) Prevailing Corruption preventing favorable implementation. Across the word, our activities in pharmacy are suspected. Latest blockbuster book “BOTTLE OF LIES” by Ebans which she wrote after exposure of Ranbaxy scandal in USA, exposing that concern is there in developed countries too what to imagine for country like India. Few examples in her book say that people outside the FDA began noticing problems with generic drugs too. Eban documents growing skepticism toward some generics among doctors in the U.S. and Africa. After numerous cases in which patients experienced problems after switching from brand-name drugs to generics, many medical professionals began avoiding prescribing certain generic drugs. In these countries major suppliers of generics are from India and China.

c) Influence of Corporates and Regulatory bodies while making decision affects the process.

HUMAN

B) Ground Reality:

a) Despite being such an important profession, head of any Pharma-Committee is mostly from other profession. Pharmacists are hardly considered at the helm of the affairs. PHARMACISTS ARE THEMSELVES SUBSTITUTED. At least professional having exposures to ground realities should be involved to carve out the relevant and practical policies.

b) Registration of new brands at state level also flooding the market with counterfeit and spurious medicines. Involving central authorities with computerization linking all states under one software may reduce corruption and improve monitoring.

c) Appointment of insufficient number of drug inspectors loosens the control. Today most of the drug offices are in shabby buildings merged with food department speak of low importance.

d) Interest of budding practicing pharmacist is not governed by law in terms of salary and appointment of pharmacist as head of pharmacy department in hospital. Starting salary for new pharmacist in north India is as low as 7000/pm.

DISCUSSION

Wish of leadership to provide economical medicine of good quality is clear but measures adopted till date were not successful. Unless correct reason is known we cannot find correct solution. In this article, we have tried to address some ground realities related to generic medicine in domestic Indian market (in overseas market too), So that leadership can attempt meaningful measures. Like in developed countries improving QUALITY through stringent implementation of policies and law and thru academics will help in major way. Rest will be achieved by addressing issues in practical manner. This will protect our business and reputation globally too. In our country OTC product list is not declared officially. Clearly speaks about the belief system of Drug Controller, funny thing is that everything sales OTC. Pharmacist also needs to prove their worth in this matter. Ministries and bodies like IMA, PCI, CDSCO should involve practicing pharmacist in related process. Influence from trade and manufacturers' association should be balanced with national interest because at some level, nothing can be more important than National Interest.

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