ORIGINAL RESEARCH PAPER

Management

GENERIC MEDICINES MYTH AND REALITY

KEY WORDS:

Proff. Dr. Suresh Abhyankar

Balaji Institute of Modern Management, SBU Pune Maharashtra

INTRODUCTION

With high propaganda by the government mechanism and AYUSH department about generic medicines many people have started thinking that generic medicines is something new that has been started by this government for the welfare of the common people. How far is it true? What is generic medicine? Is it beneficial or not? This research article tries to clear the MYTH to find the realities about generic medicines.

A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. The brand may have various salts, chemicals mixed together in various proportion through research and development and patented as a specific name created by them under their company brand. When it gets sold as generic medicine the manufacturers cannot mix the proportion in to one medicines but are required to sell the dosages of separate salts as separate generic medicine and one tablet/capsule of brand gets divided in to two/three/four different generic medicines. So, a person using brand takes one tablet/capsule and person using generic medicine takes multiple tablets/capsules.

Depending on who is manufacturing the generic medicines they are divided in to Branded generic and generic-generic medicines. E.g. if say Glaxo-Smith Kline (GSK) or Lupine or CIPLA etc. known company is selling generic medicine it is called Branded Generic and all other unknown manufacturers selling generic medicines are called as Generic-Generic medicines. Branded generic has full quality control mechanism but others may or may not have it. So, it is advised to purchase Branded Generic medicines.

Generic medicines in India are cheaper versions of branded drugs that are sold after the original drug manufacturer's patent expires. They are marketed as either a salt or brand name, and must get FDA approval for prescription and consumption. Generic medicines are as effective and safe (?) as branded drugs, and contain the same active ingredients. They allow millions of Indians to access life-saving treatments, regardless of their financial status. It is believed that these medicines were introduced by current government to ensure that all and sundry can afford to buy their required quality medicines. How true is it? Is the question all the people must ask and that must be researched by researchers?

History of generic medicines: Generic medicines for consumers is a resent fact but for general practitioners (GPs) it was an age old practice. Earlier the general practitioners (GPs) used have a person called COMPOUNDER in their clinic and the clinic used to be called as dispensary (in very few villages and towns chemists stores were available). The doctors used to write prescription that the compounder will concoct (either as liquid or mixture of various salts) and give it to patients after apportioning as per dosage with instruction of consumption. Doctors used to purchase these salts (now called as molecules) and syrups in bulk and store at their dispensary these syrups and salts are the early generic medicines. Many chemist shops used call themselves dispensing chemists as they would sale the concoctions as per the prescriptions. Over a period of time many medicine manufacturers started selling some the most used compounds in tablet form (e.g. APC- Analgene, Paracetamol & Codeine) to doctors in bulk saving their cost of employing compounders. At this juncture the compounders started their own practice collecting a license to do so and they were called LCPS doctors (licentiate Certified Physician and surgeon). The GPs would buy a tablet for say 1 paisa and charge the patient 50 paisa per tablet making good amount of money without offending the patient. Over a period, many people started manufacturing such formulations at home (generally in kitchen or spare bathroom) or used loan licensing arrangements with small time drug manufacturers/ tablet manufacturers who had spare capacity. These people many times had no license to manufacturer drugs and used un-purified chemicals (chemicals have standard purity levels in IP (Indian purity) and BP (British Purity) grade and sold these drugs at HIGH margins to chemist shops and GPs and made profits. These people even copied patented products of reputed companies and sold at lower price (without quality control) that affected business of these companies to a large extent. Government had regularised these arrangements under rule 75A and Form 28 of the Drugs and Cosmetics Rules, 1945, allowing companies to manufacture drugs using another firm's facilities and personnel but it was largely flouted.

When the world's patent laws were not applicable in India, companies like Ranbaxy and Dr. Reddy's laboratory collected samples of popular branded medicines/drugs from developed world and copied them to sell as their own brands and became big and famous in India. Now that the patent laws have become applicable they have cleverly contracted the original manufacturers to supply these medicines to USA and Europe procuring US drug controllers quality certificates and maintained their business at high level. They have now even opened their manufacturing facilities in those countries.

In 2017 government banned loan licensing arrangements and sell of branded medicines of other companies and allowed to sell non-patented drugs by their generic names and put in restrictions on trade margins and end price to consumers. In 2022, toxic cough syrups made by two companies in India were linked to the deaths of 70 children in The Gambia and 19 in Uzbekistan. According to the World Health Organization (WHO), the products had excess levels of diethylene glycol. But government failed to ensure quality control mechanism leading to deaths of many patients globally after consuming these medicines exported by Indian companies reducing reliability of Indian companies.

Objectives: This paper tries to find answers to following questions and so they become objectives

1. Why branded medicines are expensive?
2. Can we trust the generic medicines for their quality?
3. Can the generic medicines be sold at lower than their current prices?

Findings

1.Medicine manufacturing costs are same for branded and generic medicines, branded medicines are sold at higher price because the manufacturer is trying to recover their costs of researching the medicines, trials first on animals and then humans that last for many months or even years with many risks and expenses. Then the medicine is presented to

the various drug authorities to prove that the medicines are really useful and safe for human consumption. Then the manufacturers procure PATENT (again time consuming and expensive process) for the drug so that no one else can copy and sale it without their permission. Once, the drug authorities give permission to market the medicines the drug manufacturers require to take various conferences where they show the results of trials and request the doctors/ surgeons to start using the drug. These conferences are also expensive and above all the Medical representatives are required to popularise the drug amongst the medical fraternity and make the chemists to store and sale it. All these processes are expensive and time consuming and for recovering these costs (they are in business not charity) they sale the product at higher profits as early as possible. Once the duration of patent is over anyone can manufacture it and sale at low prices as generic medicine and not as a brand of the company that researched and developed it.

2.Indian customers are not easily ready to purchase unbranded medicines feeling afraid about their quality because of this government mechanism- AYUSH ministry had to promote them wholeheartedly. These customers easily purchased branded medicines manufactured on loan licencing or by copying patent ended drugs as the Indian manufacturers promoted them vociferously. In loan licencing arrangements the manufacturer was responsible for the quality of drugs being manufactured for the loan licensor. After ban on the loan licensing arrangements to promote Indian medicine industry and reduce prices of medicines, many new medicine manufacturers emerged across the country but without any quality control mechanism many of these manufacturers are manufacturing drugs and medicines of low quality, some of them even importing them from China through legal and illegal mode to make money and sell in India. Currently more than 10000 drug manufacturers are operative in India. Out of these 10000 around 7673 pharma industries are in 118 clusters, 1995 (26%) are micro industries, 2393 (31.2%) are small industries, 2331 (30.4%) are medium scale industries and 954 (12.4%) are large industries. Most of the large scale pharma industries are located in the clusters of Mumbai, Thane, Baddi, Puducherry, Chennai and Secundarabad. That means around 2500 manufacturers are located in various locations (not in industrial estates or drug manufacturing clusters) and may not have any quality control mechanism and government control making them doubtful about their quality.

3.Drug pricing is largely controlled by Central government, if they want to make it cheap they can make it without any problem. Earlier before GST came in to effect the taxation was as follows

i. Lifesaving medicines "0%" VAT (value added tax)
ii. Other medicines "5%" VAT+ 6 to 12% Excise duty
iii. OTC (over the counter) product "12%" VAT+ 12% excise duty

Under GST regime the taxation structure differs to a large extent with many slabs like 0, 5,12,18 & 28% GST as per the category decided by the government. The authorities claim that normal regularly medicines did not get affected by change over from VAT to GST as follows

Particulars	Pre-GST (Rs.)	Post-GST (Rs.)
Cost of manufacturing (A)	100	100
Excise duty 6% on 65% of MRP (B)	3.90	
VAT 4% on A+B	4.16	
GST at 12%		12
Final price	108.06	112

Fig.1 Comparison of VAT and GST considering GST at 12%, for GST at 18 and 28% medicines become expensive

If we consider the above data, it is in the hands of government to make the drugs cheaper or expensive after and before introduction of GST. People got very angry when during the CORONA time the Kits were attracting 28% GST.

CONCLUSIONS

From the above information and finding we can conclude as follows

1. Branded medicines are expensive because the organization is trying to recover costs of research, experiments on animals and then humans, deciding the dosage, and getting permissions to sale from various drug authorities.
2. Branded-generic medicines can be trusted with eyes closed, but generic-generic (unknown manufacturers) are doubtful
3. Generic and even branded medicines can be sold and much lower prices provided government reduces the taxes on them.

Suggestions

Considering all the information one can give following suggestions

1. Government should create a system where all the medicine manufacturers are FORCED to follow strict quality control mechanisms
2. Government should consider reducing medicine prices by keeping only 0 & 5% GST rates on them

REFERENCES

1. https://www.google.com/search?q=generic+medicines&rlz= 1C1CHBF_enIN1085IN1085&oq=generic+medicines&gs_lcrp=EgZjaHJvbWUyBggAEEUYOzIJCAEQRRg5GIAEMg4IAhBFGCcYOxiABBiKBTIGCA
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6515776/
3. https://pharmadocx.com/loan-license-for-drug-manufacturing/#:~:text=Regulatory%20Basis%3A%20The%20concept%20of,another%20firm's%20facilities%20and%20personnel.
4. https://blog.pharmahopers.com/loan-license-and-third-party-manufacturing-ban-in-pharmaceutical-industry
5. https://pharmaceuticals.gov.in/sites/default/files/Final%20Report-Survey%20of%20Pharma%20Clusters.pdf
6. https://en.wikipedia.org/wiki/Pharmaceutical_industry_in_India
7. https://cleartax.in/s/impact-of-gst-rate-on-pharmaceutical-industry