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A Review Article On The knowledge, Attitude and Practice of Generic and 8Ethical Medicines

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Abstract: Nowadays, brand-name drugs are becoming an out-of-pocket expense which comprises 80% of total health-care expenditures. However, generic drugs are less expensive than brand-name drugs with the same therapeutic effect, but many doctors hold negative views of generics and resist prescribing the generic drug. Branded medicines are manufactured following strict standards. Generic drugs are formulated differently, but they still work in the same way. This study was designed to assess the knowledge, attitude, and practice of doctors toward generic medicines.

Keywords: Generic drug, Branded medicines

Introduction : Ethical pharma business is the marketing of new drugs that have been extensively tested for efficacy, safety and quality. These drugs usually go through a rigorous R&D process, including preclinical and clinical trials, before they are approved for selling. Example: developing new cancer treatment drugs or vaccines. While generic pharma business involves the production and sale of generic drugs, which are bio-equivalent to brand-name drugs. These drugs have the same active ingredients, dosage form, strength, route of administration and intended use as the original brand-name drug. Generic drugs are cost-effective drugs, competing on price and relying on higher volume sales. Example: drugs like ibuprofen, paracetamol are readily available from different manufacturers at lower prices.Let's understand what we mean by "branded medicine" and "generic medicine". Branded medicines or ethical medicines, also known as brand-name, are the original medications developed by pharmaceutical companies. They go through a process of research, development, clinical trials and drug department approval before entering the market.

On the other hand, generic medicines are identical copies of the original brand-name drugs. They contain the same active ingredients, in the same doses, and are intended for the same use as their ethical counterparts. Interestingly, generic drugs are sometimes created by the same manufacturers that create branded drugs.

Unlike branded medicines, generic medicines are cheaper because they do not have the same research, development, marketing and promotion costs associated with them.

However, it is important to note that the drug department ensures that both branded and generic drugs perform the same way, meet the same standards of quality and manufacturing, and have the same risks and benefits.

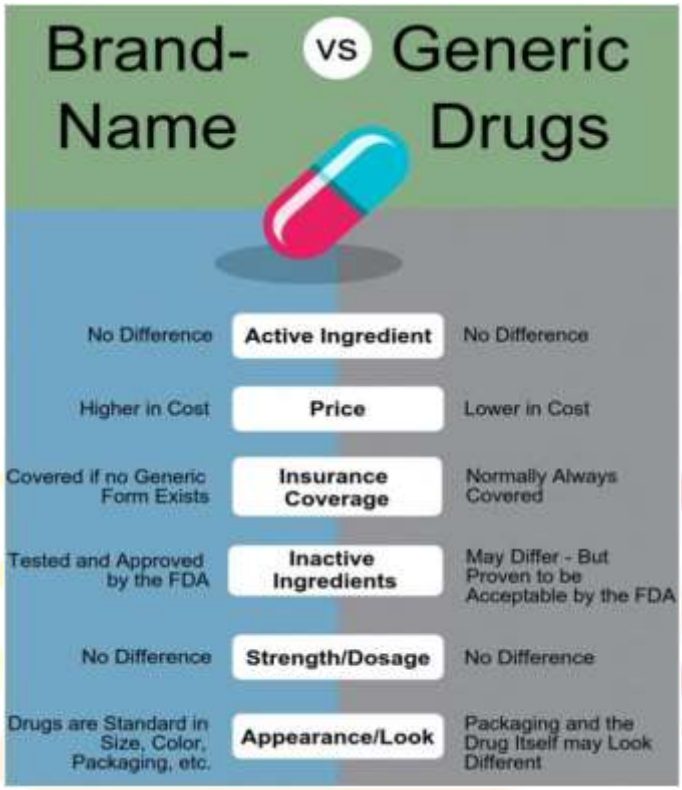
Branded medicines and generic medicines are identical in terms of doses, planned use, route of administration and side effects. The main difference lies in their pricing and branding.

While choosing a doctor, many patients find themselves at crossroads. Do you choose the doctor who offers you the generic version of medications? Or do you opt for one that prescribes branded medicine in their dealings with patients?

Fortunately, there are still doctors out there that place their patient's interests above their own. These professionals understand that long-term relationships are key to success, and they act accordingly

The difference between generic and ethical pharma business are:

Generic drugs are more affordable than their brand-name counterparts. Generic drugs are manufactured once the patent protection of the brand-name drug expires, allowing other pharmaceutical companies to manufacture and sell the generic version. This increased competition in the market often leads to lower prices for generic drugs, making essential medicines more accessible to a larger population.



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Ethical pharmaceutical companies, on the other hand, often have higher prices for their newly-developed drugs to recoup their R&D costs and invest in future research. These drugs may offer novel therapeutic benefits or improved efficacy compared to existing treatments. The higher prices can make these drugs less accessible to some patients, particularly those without adequate healthcare coverage

Generic drugs provide cost-effective alternatives to brand-name medications, allowing patients to access essential treatments at lower prices. Ethical pharmaceutical companies develops new drugs that can improve patient outcomes and address unmet medical needs. Both generic and ethical pharma businesses are important for healthcare industry.

While generic drugs shows bioequivalent to the brand-name drugs but their manufacturing processes may differ. This can result in slight variations in the rate and extent of drug absorption, which may not be clinically significant for most patients. However, in some cases, patients may respond differently to generic drugs compared to the brand-name version, highlighting the importance of monitoring and individual patient care.

Stronger marketing and advertising campaigns are adopted by ethical pharma companies to promote their branded drugs, while generic pharma companies focus on distributing their products largely through pharmacies and hospitals.

Direct-to-consumer advertising method is adopted by ethical pharma companies to create demand for their drugs, while generic pharma companies rely on healthcare professionals to prescribe their drugs based on their cost-effectiveness and therapeutic equivalence.

There is high level of brand recognition and trust among consumers of ethical pharma products due to their established reputation, while generic pharma companies may need to build trust by consistently delivering high-quality, affordable drugs.

Generic pharma companies build relationships with distributors and pharmacies to ensure their products are widely available, while ethical pharma companies may engage in partnerships with healthcare providers and institutions to conduct research and promote their branded drugs.

Why do generic medicines often cost less than the brand- name medicines?

Generic drugs are approved only after a rigorous review by FDA and after a set period of time that the brand product has been on the market exclusively. This is because new drugs, like other new products, are usually protected by patents that prohibit others from making and selling copies of the same drug.

Generic drugs tend to cost less than their brand-name counterparts because generic drug applicants do not have to repeat animal and clinical (human) studies that were required of the brand-name medicines to demonstrate safety and effectiveness. This abbreviated pathway is why the application is called an “abbreviated new drug application.”

The reduction in upfront research costs means that, although generic medicines have the same therapeutic effect as their branded counterparts, they are typically sold at substantial discounts, an estimated 80 to 85% less, compared with the price of the brand-name medicine. According to the IMS Health Institute, generic drugs saved the U.S. healthcare system nearly $2.2 trillion from 2009 to 2019.

When multiple generic companies are approved to market a single product, more competition exists in the marketplace, which typically

results in lower prices for patients.

Bringing more drug competition to the market and addressing the high cost of medicines is one of FDA's top priorities. In 2017, FDA announced the Drug Competition Action Plan (DCAP) to further encourage robust and timely market competition for generic drugs and help bring greater efficiency and transparency to the generic drug review process, without sacrificing the scientific rigor underlying our generic drug program.

How Does FDA monitor side effects or safety issues with generic medicines?

FDA takes several actions to ensure safety and quality before and after a new or generic medicine is approved. When a generic drug application is submitted, FDA conducts a thorough examination of the data submitted by the applicant and evaluates information obtained by FDA investigators while inspecting the related testing and manufacturing facilities to ensure that every generic drug is safe, effective, high quality, and substitutable to the brand name drug.

FDA staff continually monitors all approved drug products, including generics, to make certain the medicines at all levels of the supply chain, from active pharmaceutical ingredients (APIs) to products being sold to consumers, are safe, effective, and high quality.

FDA also monitors and investigates reports of negative patient side effects or other reactions. The investigations may lead to changes in how a product (brand-name and generic) is used or manufactured, and FDA will make recommendations to health care professionals and the public if the need arises.

MedWatch is the FDA's medical product safety reporting program. Health professionals, patients and consumers can use MedWatch to voluntarily report a serious adverse event, product quality problem, product use/medication error, or therapeutic inequivalence/failure that is suspected to be associated with the use of an FDA-regulated drug, biologic, medical device, dietary supplement or cosmetic.

Branded versus Generic (Branded-Generic) Medicines-For Whose Benefit?

Since there is not a substantial difference in the MRPs of these products, this higher trade margin is possible because of the very low PTR for the branded generics. PTR reflects the manufacturing cost of the product.

This naturally leads to a question about the quality of generic drugs, supposedly produced at lower production cost?

This justifies the apprehension about theirquality in the minds of the clinicians and patients. There exists a widespread belief among people and dispensing chemists that a branded product is better in terms of quality and safety than the generic.

Many reports comparing the effectiveness of branded generics and their branded counterparts are available. Many studies are conducted to test the therapeutic bio equivalence of generic drugs even prior to marketing and there are number of published studies assuring the safety and efficacy of these generic drugs.

There are also many studies reporting that generic antibiotics behave differently from brand products against pathogenic microorganisms have also been raised about the efficacy of generic antibiotics, based on complaints from the medical community reported in the literature and at international meetings have also reported comparable values of Minimum Inhibitory Concentrations for the local And multinational brands of 1st, 2nd and 3rd generation cephalosporins against clinical isolates of S.aureus.

Literature Review

Aivalli, Elias, Pati, et al. (2018) examined the branded and generic medicines quality & give details on negative observation of patients towards generic medicines. Finding of research study shows that generic and branded medicines alternatives tested were of comparable on quality factor. Result of quality test show that perception of patients' & health workers' on quality were mostly in favor of branded medicine as compare to generic medicines. Negative point of view on quality of medicine in company with other factors leads towards selection of more costly medicines in pvt. Sector.

Tripathi & Bhattacharya (2018) found that generic prescription concept is broadly established in various parts of the world. However, it failed to gain recognition because of factors like distrust on quality of product and its non-availability. Finding of the study shows that attitude and knowledge for generic medicine among respondant were not good.

Das, Choudhury, Maity, Hazra, Pradhan, Pal, et al. (2017) evaluated the attitude and experience of patients who purchases and consume generic drugs from fair price medicine shop. Finding of the study shows that there are various factors that influence the patients perceptions towards generic medicines such as non availability of medicines and distrust on these medicines usually leads to professed inferior quality and fakeness in these drugs. Attitude and experience for generic medicines are found non uniformity among physicians across the world.

Alrasheedy et al (2021) found that patients and medicine consumers usually prefer original branded medicines as compare to generic drugs. Furthermore, most of literature reviewed negative perceptions and misconceptions towards generic medicines among medicine consumers and patients. This research study focuses on particular population such as epilepsy or renal transplant patients. These patients reported resistance and negative perception towards generic medicine usage. Medical condition of the patient, their severity or seriousness, health care professionals recommendations, difference in prices, earlier experience with generic medicines

and information or awareness for generic medicines are found as significant factors that influences decisions of patients to use branded or generic medicine.

Generic medicine Experiments in India:

The Tamil Nadu and Rajasthan governments procure generic name medicines at extremely competitive prices year after year, and crores of drugs are in use in their public health systems, thanks to the quality assurance systems in place.The success of the drug procurement system in these two states should counter the defeatist narrative that insists that generic medicines can never be good.This is not to underestimate the challenges in ensuring quality generic medicines countrywide, but the critics from the medical

profession are doing the poor patient enormous disservice by swallowing the disinformation from the pharmaceutical industry about the general lack of bioavailability of generics as compared to brands.
When a pharma company invest & develop any new drug & earn patent rights for it, then is called branded drug (BD). The duplicates of branded drugs are known as generic drugs. They have following differences:
Production: Only Company with patent rights are allowed to manufacture Branded Drug. Once patent lapses, other companies are allowed to produce generic drugs.
Cost: Unlike generic drugs, branded drugs incur high cost due to high investment research & development.
Ingredients: The active ingredient (the one which cure the disease) of both drugs are same but the differs in colour, shape or taste.Affordable, effective & easy drug access important for "universal healthcare". So, India has decided to bring a law for doctors to prescribe generic medicines which have certain issues:
Implementation: Lower awareness and corruption have given rise nexus between Doctors chemists & pharma sector. So, public awareness via digital media along surveillance mechanism to curb nexus
International pressure: Big western pharmaceutical lobbies may back stringent IPR rigme & compulsory licensing. They may blame India to breach TRIPS agreement and drag into WTO. But recent UN report has given precedence to human rights over patent rights which support India's move for affordable generic price to improve health care
Supply side challenge: India is import driven country for active pharmaceutical ingredient and already facing challenge of substandard quality of generic drugs. Along with this current move may reduce FDI inflow in pharm sector and slowdown research & development in domestic pharma companies. However, India has taken steps like 'India Pharma & India Medical Device 2017' and new IPR policy that offer incentive & ease of doing business in India. India should adopt stricter accreditation and inspection rules for generic drugs
Jan Aushadhi Scheme :
The Government has launched 'Jan Aushadhi Scheme' to make available quality generic medicines at affordable prices to all, especially the poor, throughout the country, through outlets known as Jan Aushadhi Stores (JASs).
Under the Jan Aushadhi Scheme, the State Governments are required to provide space in Government Hospital premises or any other suitable locations for the running of the Jan Aushadhi Stores (JAS).
Bureau of Pharma PSUs of India (BPPI) is to provide one-time assistance of Rs.2.50 lakhs as furnishing and establishment costs, start up cost for setting up a Jan Aushadhi Outlet.
Any NGO/Charitable Society/Institution/Self Help Group with experience of minimum 3 years of successful operation in welfare activities, can also open the Jan Aushadhi store outside the hospital premises. A margin of 16% on the sale price is built in the MRP of each drug.
In addition, the JAS are eligible for incentive linked to sale of medicines @ 10% of monthly sales amount, subject to a ceiling of Rs.10,000/- pm for a period of first 12 months. In case of Stores opened in North Eastern States and other difficult areas i.e., Naxal affected areas/Tribal areas etc., the rate of incentive is15% of monthly sale amount, subject to a ceiling of Rs.15,000/- per month.
At present more than 175 Jan Aushadhi Stores have been opened across various States/UTs. JAS are opened on the locations as requested by the entity intending to open. The steps are also taken to open Jan Aushadhi stores in all AIIMS, prominent Hospitals, Medical Colleges under the Ministry of Health & Family Welfare.

Indian Government Initiative:

The Medical Council of India (MCI), in an amendment to the Code of Conduct for doctors in October 2016, has recommended that every physician "should prescribe drugs with generic names legibly … and he/she shall ensure that there is a rational prescription and use of drugs."
How the MCI is going to ensure rational prescription and use, without a framework to measure the same, should be looked into seriously.
Rational use and prescription depends on the doctor, the pharmacist, the regulator, and the consumer.
Some minimum prerequisites for rational use are: prescription-only medicines (Schedules G, H, H1 and X) must not be available freely over the counter; doctors and their professional bodies along with regulators must ensure there is no misuse of antibiotics and critical drugs; and the removal of all irrational/harmful/useless medicines, both FDCs and unscientific single ingredients, must be ensured.
Practical guidelines for rational use and prescription audit of medicines must be developed and implemented seriously by all doctors.
Branding of off-patent drugs needs to be discouraged as is the practice in well-regulated countries.
A time bound plan to make generic prescriptions mandatory will also prepare Indian pharma's vast supply chain of 800,000 wholesalers and retailers to get used to the new initiative progressively. India's 800,000 retailers have thrived because it is a profitable high-margin business.

Conclusion: When you're looking for a drug to treat a certain health issue, you have a choice between branded and generic medicines. Both types of medicines are formulated to have the same effect.Branded medicines are manufactured following strict standards. Generic drugs are formulated differently, but they still work in the same way. Both types of drugs have advantages and disadvantages.Choose the type that best suits your needs. People who have specific health conditions may find that branded medicines work better for them than generic medicines.
Branded medicines are often more expensive than generic medicines, so those on a budget may find that generic medicines are a better option. You may be able to save money on the long term medications by switching to generic medicines.

Reference:

[1] Dunne SS, Dunne CP. What do people really think of generic mediciness?A systematic review and critical appraisal of literature on stakeholder perceptions of generic drug. BMC Med. 2015;13:173. doi: 10.1186/s12916-015-0415-3. [DOI] [PMC free article] [PubMed] [Google Scholar]

[2] Kumar AS, Chen LC, Choudhury M, Ganju S, Mahajan V, Sinha A, et al. Financing health care for all: Challenges and opportunities. Lancet. 2011;377:668–79. doi: 10.1016/S0140-6736(10)61884-3. [DOI] [PubMed] [Google Scholar]

[3] Haas JS, Phillips KA, Gerstenberger EP, Seger AC. Potential savings from substituting generic drugs for brand-name drugs: Medical expenditure panel survey, 1997-2000. Ann Intern Med. 2005;142:891–7. doi: 10.7326/0003-4819-142-11-200506070-00006. [DOI] [PubMed] [Google Scholar]

[4] Chong CP, Bahari B. Generic subtitution in community pharmacies of Penang area. Malays J Pharm Sci. 2005;3:74. [Google Scholar]

[5] Alrasheedy AA, Hassali MA, Aljadhey H, Ibrahim MI, Al-Tamimi SK. Is there a need for a formulary of clinically interchangeable medicines to guide generic substitution in Saudi Arabia? J Young Pharm. 2013;5:73–5. doi: 10.1016/j.jyp.2013.06.006. [DOI] [PMC free article] [PubMed] [Google Scholar]

[6]Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. Indian J Pharmacol. 2011;43:131–6. doi: 10.4103/0253-7613.77344. [DOI] [PMC free article] [PubMed] [Google Scholar]

[7] Shrank WH, Liberman JN, Fischer MA, Girdish C, Brennan TA, Choudhry NK. Physician perceptions about generic drugs. Ann Pharmacother. 2011;45:31–8. doi: 10.1345/aph.1P389. [DOI] [PubMed] [Google Scholar]

[8] Kumar R, Hassali MA, Saleem F, Alrasheedy AA, Kaur N, Wong ZY, et al. Knowledge and perceptions of physicians from private medical centres towards generic medicines: A nationwide survey from Malaysia. J Pharm Policy Pract. 2015;8:11. doi: 10.1186/s40545-015-0031-9. [DOI] [PMC free article] [PubMed] [Google Scholar]

[9] Jamshed SQ, Ibrahim MI, Hassali MA, Masood I, Low BY, Shafie AA, et al. Perception and attitude of general practitioners regarding generic medicines in Karachi, Pakistan: A questionnaire based study. South Med Rev. 2012;5:22–30. [PMC free article] [PubMed] [Google Scholar]

[10] Chua GN, Hassali MA, Shafie AA, Awaisu A. A survey exploring knowledge and perceptions of general practitioners towards the use of generic medicines in the northern state of Malaysia. Health Policy. 2010;95:229–35. doi: 10.1016/j.healthpol.2009.11.019. [DOI] [PubMed] [Google Scholar]

[11] Hassali MA, Shafie AA, Awaisu A, Ibrahim MI, Ping CC, Jamshed S. Physicians' views on generic medicines: A narrative review. J Generic Med. 2010;7:30–9. [Google Scholar]

[12] Dunne SS, Shannon B, Cullen W, Dunne CP. Beliefs, perceptions and behaviours of GPs towards generic medicines. Fam Pract. 2014;31:467–74. doi: 10.1093/fampra/cmu024. [DOI] [PubMed] [Google Scholar]

[13] Davit BM, Nwakama PE, Buehler GJ, Conner DP, Haidar SH, Patel DT, et al. Comparing generic and innovator drugs: A review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43:1583–97. doi: 10.1345/aph.1M141. [DOI] [PubMed] [Google Scholar]

[14] Amit G, Rosen A, Wagshal AB, Bonneh DY, Liss T, Grosbard A, et al. Efficacy of substituting innovator propafenone for its generic formulation in patients with atrial fibrillation. Am J Cardiol. 2004;93:1558–60. doi: 10.1016/j.amjcard.2004.02.071. [DOI] [PubMed] [Google Scholar]

[15] Araszkiewicz AA, Szabert K, Godman B, Wladysiuk M, Barbui C, Haycox A. Generic olanzapine: Health authority opportunity or nightmare? Expert Rev Pharmacoecon Outcomes Res. 2008;8:549–55. doi: 10.1586/14737167.8.6.549. [DOI] [PubMed] [Google Scholar]

[16] Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: A systematic review and meta-analysis. JAMA. 2008;300:2514–26. doi: 10.1001/jama.2008.758. [DOI] [PMC free article] [PubMed] [Google Scholar]