GENERIC MEDICINES IN PUBLIC HEALTH

PREPARED BY: DR. SUDHA CHANDRASHEKAR

DR. ANUSHREE

INTRODUCTION

Since the ancient times medicines and health go hand in hand. From the development of vegetable herbs and plants as potent cure for deadly diseases, the art and science of medicine has been ever evolving. Historical texts show evidence of using saffron, caffeine, euphorbium and other herbs to treat different ailments of the human body. This was followed by advancements in modern science leading to the development and use of medicines like morphine, quinine, aspirin, paracetamol, phenylhydrazine etc. The evolution of modern science is greatly attributed to the development of medicines and vaccines for some of the most pressing public health issues. Today, thousands of medications are available that can prevent, treat, and reduce the severity of illnesses that would have been fatal just a few generations ago.

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.[1]

The World Health Organization defines a generic medicine as a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights[2].

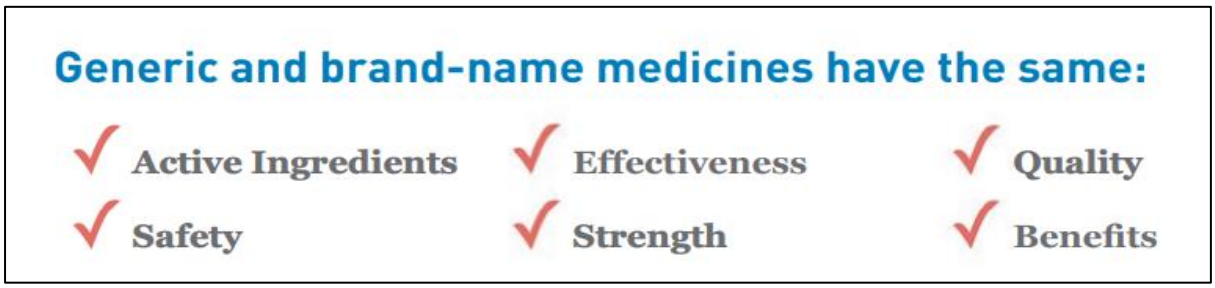
[1] https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers

[2] Indian J Med Res 147, May 2018, pp 442-444 Quick Response Code:

The US Food and Drug Administration [FDA], which regulates the pharmaceutical market in the United States defines generic medicines as:

–a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use
–copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use[3].

Generic drugs are developed based on bioequivalence wherein these drugs are equally as effective and show similar results as that of the brand name medicine. It is one of the main principles underpinning the safe and effective use of generic medicines. The generic drugs are similar to brand medicines in terms of its effectiveness, safety, strength, quality and benefits. It is mandatory to have a similar active ingredient and route of administration for the generic medicines. The generic medicines are manufactured under the similar environmental and infrastructural specifications as that of brand medicines. However, they can differ in terms of the inactive ingredients used, the colour, flavours, taste and shapes.



Source: https://www.fda.gov/media/107601/download

Generic drugs undergo rigorous scrutiny and review before they are deemed fit for dispensing and market use by the FDA in USA. There are other similar agencies that carry out approval processes for these medicines in the respective countries and regions.

In India, the Central Drugs Standard Control Organization (CDSCO) is responsible for approving drugs which is headed by the Drugs Controller General of India (DCGI). What makes these generic drugs cheaper than brand drugs and what exactly is the rationale behind the promotion of generic drugs is still a *terra incognita* to the medical fraternity as well as the common consumers across the world.

There are many legal and regulatory issues along with quality concerns associated with the use of the generic products. Lately, bilateral international agreements called Free Trade Agreements (FTA), delaying tactics by originator companies like strategic patenting and litigations on generic manufacturers have been a major setback for the generic medicine industry. These issues need to be addressed to optimize use of generic medicines. The

DOI: 10.4103/ijmr.IJMR_1940_17
[3] https://www.fda.gov/drugs/generic-drugs/what-approval-process-generic-drugs

sustainability of generic medicines sector is crucial for improving access to essential medicines for the world[4]

WHAT MAKES GENERIC MEDICINES CHEAPER?

Whenever a new drug is developed, the developing brand gets a patent for 20 years in order to recover the costs of drug development research, investigation, clinical trials and manufacturing. They also spend a lot on its branding and marketing in the national and international markets. The cost of developing a new drug also involves finances required for attending conferences, filing registrations and other registration processes. Once the patent period is over the drug is available in the market with its formula available to be used by other manufacturers. This is what makes the drug generic. Since now the manufacturers of generic drug don't have to spend on overheads, it just takes into account the manufacturing and packaging charges of the medicines. This makes the generic drug lot cheaper than the branded drug. Another common cause of drugs made generic is when the medicine is of prime public health use or in the interest of fighting a deadly disease, saving multiple lives, a litigation can be fined in the international law court and if agreed upon, the drug formula is made public for the use by different countries. Branded drugs are sold under different brand names depending on the manufacturer. The generic drugs are free from proprietary rights and hence their nomenclature is completely different and universal. These drugs are given a standard International non-proprietary name (INPN) that is universally accepted and agreed upon. All the member countries of WHO have accepted this protocol and follow this nomenclature. Thereon, the drug is sold under that INPN name.

Generic medicines are manufactured by several pharmaceutical companies and they may also be sold as commodity or branded generics. The term "branded generics" refers to the generic product that is branded by a particular pharmaceutical company. This category of branded generics resembles the formulations referred to as non-branded generics (commodity generics) worldwide. Branded generics are more expensive than non-branded generics and find a market because of promotion by pharmaceutical companies and huge profit margins for retailers.

BENEFITS OF GENERIC DRUGS

Most countries are facing escalating health care expenditures. Escalating costs and affordability of medicines for both governments and patients has become a global challenge. In an era of rapidly rising health care costs, generic medicines provide a less expensive alternative to branded medicines. The issue of access and affordability is thus addressed by using generic medicines that contribute to substantial savings in medicines expenditure [5]

Generic medicines have already been extensively used by developed nations like USA, Canada, Australia with India and China being the major exporters of generic medicines. One of the greatest benefits of using Generic medicine is the cost effectiveness of these drugs.

[4] https://www.researchgate.net/publication/282278221_Generic_Medicines_Issues_and_relevance_for_global_health

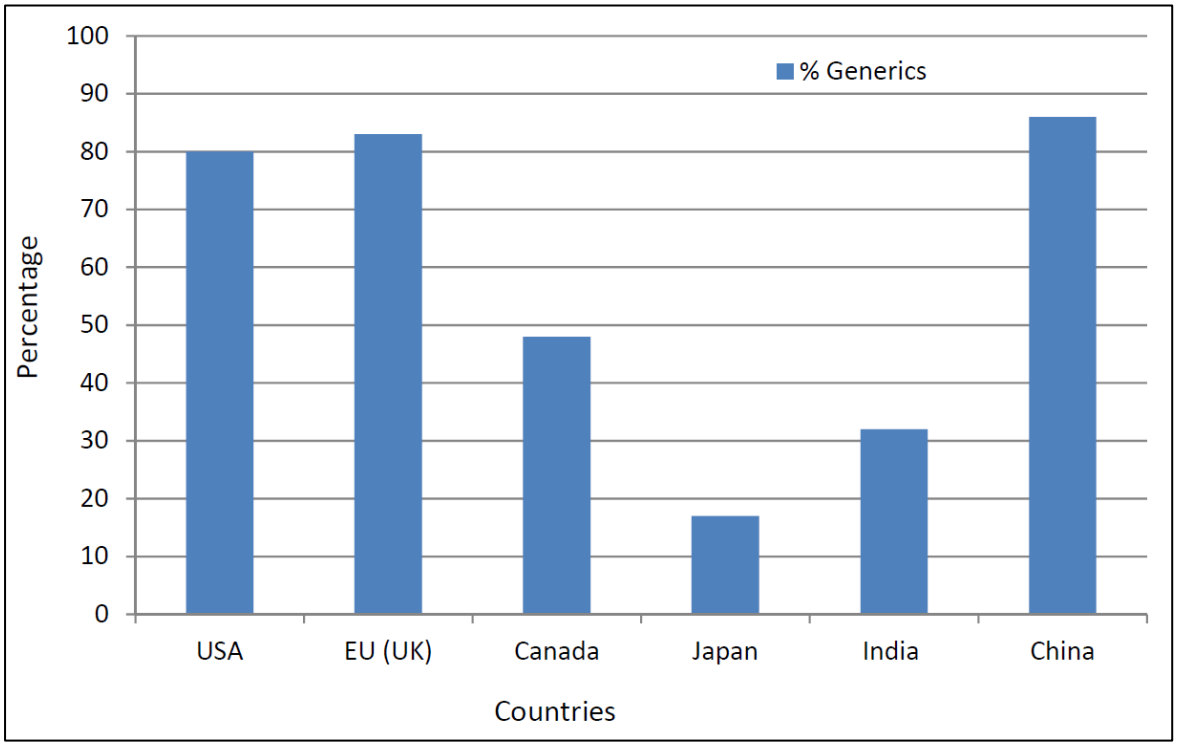
The use of generic medicines is often promoted as a measure to reduce medicine costs and increase consumer access and can be included in NMPs as part of strategies to encourage the cost-effective use of medicines by health professionals and consumers

Generic manufacturers provide medicines at lower costs by avoiding expenses related to research, development, marketing, and advertising. They offer cheaper alternatives once patents for innovator drugs expire, ensuring greater affordability for patients. Over the past decade, the use of generic medicines has saved over $1.2 trillion in the USA alone. Competition among generic manufacturers further reduces prices, improves access, and guarantees a continuous supply, even during unexpected healthcare demands or after the innovator drugs exit the market.

Generic medicines are particularly beneficial for patients with chronic conditions, as lower costs lead to better adherence to long-term treatments.

Despite the rising costs of developing generics due to complex molecules and stricter regulations, increased use of generics could help offset rising healthcare expenses while maintaining positive healthcare outcomes.

UTILISATION OF GENERIC DRUGS



Graph: Utilisation of Generic drugs in major economies

The use of Generic medicines has been increasing all over the world, due to the economic advantages they offer. Prescription audits have shown that the percentage of medications prescribed by generic names varies from below 50% in India, Canada, Japan, African countries to over 80% in countries like USA, UK, China and Australia. Since the mid 1970's, the global trends in the pharmaceutical industry particularly in US have been towards growth in the generic medicine sector. This was particularly seen with over 56 major pharmaceuticals losing patent coverage between 1975 to 1987. The top global markets for unbranded generic

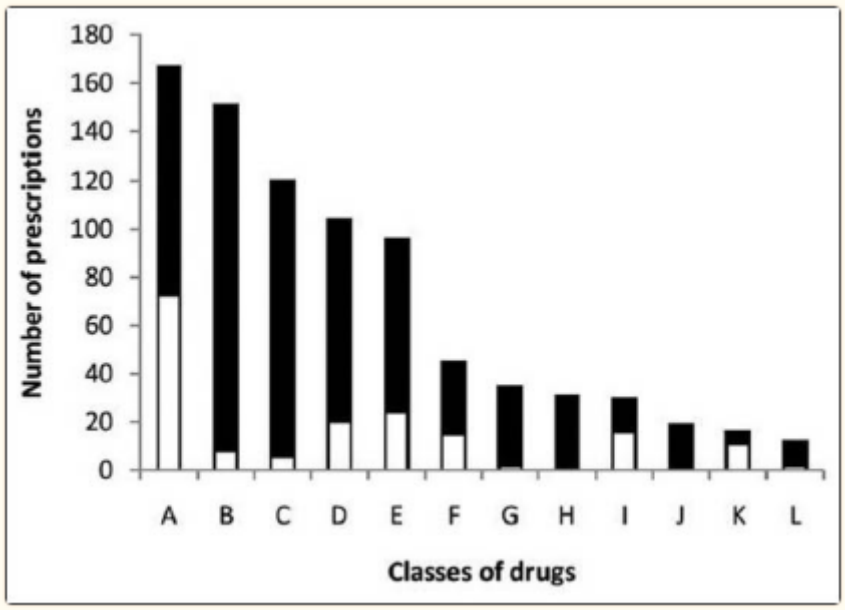
medicines are the USA, EU (Germany, United Kingdom and France), Canada, Japan, China and India[4]

The Chinese pharmaceuticals market is expected to become the second biggest market in the world and will contribute 31% of global pharmaceuticals market growth. Factors influencing China's growth include healthcare reform, which intends to provide universal healthcare to the country's residents and the country's increasingly wealthy and ageing population. In 2020, China is forecast to spend US$1 trillion on healthcare.[5]

India is one of the largest exporters of generic medicines to various countries at low cost. Indian pharmaceutical industry ranks high amongst all the third world countries in terms of technology, quality and the vast range of medicines that are manufactured. One of the biggest pharmaceutical markets in the world, India is home to several top pharmaceutical firms. The Indian pharmaceutical sector is ranked third globally in terms of volume and fourteenth globally in terms of value, according to Invest India, an agency of the Indian Government for Investment Promotion and Facilitation. Along with having more than 3,000 pharmaceutical businesses and more than 10,500 production facilities, India also has the most US-FDA compliant pharmaceutical plants outside of the United States[6]. Contrary to this less than 50% of Indian prescriptions have a mention of generic medicines

A study conducted in the tertiary care hospital of India suggests the low utilisation and prescribing habits of the generic drugs in the hospital. It was found that more than 75 percent prescriptions were by brand names. The research recommends to utilise Pharmaceutical step-therapy approach, whereby use of a first line agent, a generic alternative, is required prior to coverage of a second line agent, usually a branded product, can be a useful strategy in increasing drug cost savings.[7]

[5] https://www.gabionline.net/reports/The-generics-market-in-China
[6] https://www.databridgemarketresearch.com/reports/global-generic-drug-market#:~:text=Generic%20Drug%20Market%20Analysis%20and,pricing%20analysis%2C%20and%20regulatory%20framework.
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4171867/



A: Antiinfectives, B: gastrointestinal tract drugs, C: nutritional agents, D: antiinflammatory, E: cardiovascular drugs, F: central nervous system drugs, G: hypolipidemics, H: antiplatelets, I: hormones, J: respiratory drugs, K: anticoagulants, L: oral hypoglycaemic agents, ■ trade, ☐ generic.

Fig: Drug utilization pattern in a tertiary care hospital of India(Generic vs Trade)

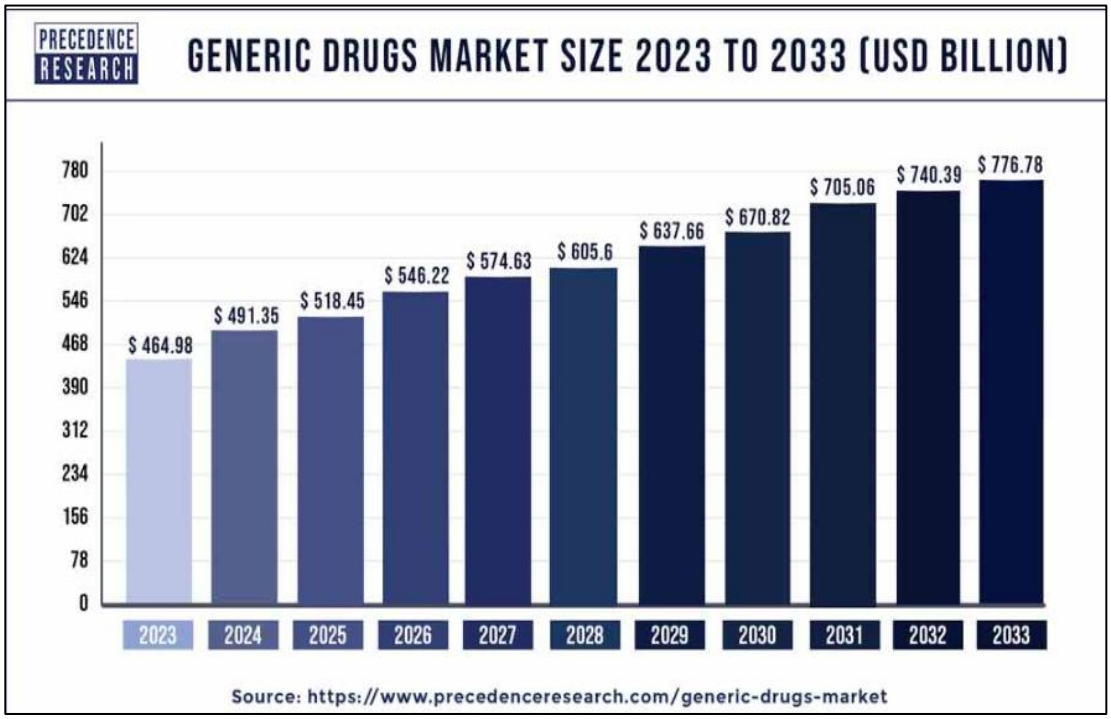
Data Bridge Market Research analyses that the generic drug market, which is USD 622.02 million in 2022, is expected to reach USD 1,323.68 million by 2030, at a CAGR of 9.9% during the forecast period 2023 to 2030.

The global generic drugs market size was valued at USD 464.98 billion in 2023 and is projected to hit around USD 776.78 billion by 2033, growing at a CAGR of 5.2% over the forecast period from 2024 to 2033. Emerging economies such as India and China hold immense potential for the market growth due to the cost effectiveness of the generic drug in these countries. Purity, potency, stability, and drug release are the crucial factors that determine the quality of generic medications, and these should be controlled within a suitable limit, range, or distribution to achieve the required drug quality. Therefore, approval required for generic drugs due to the stringent governmental regulations, which is expected to obstruct market growth.

Crucial factors accountable for market growth are:

- The low cost of generics as an alternative to branded drugs
- Large number of patents expired branded drugs
- Initiatives by governments and other regulatory bodies across the globe[8]

[8] https://www.precedenceresearch.com/generic-drugs-market



Rise in the use of Artificial Intelligence can lead to speeding up of regulatory and registration processes giving them better compliance with standards and protocols. Another boost the generic market can be achieved due to surge in Cancer cases, Cardiovascular conditions, respiratory illnesses and other non-communicable diseases. The World Health Organization estimates that each year there are between 2 and 3 million instances of non-melanoma skin cancer and 132,000 cases of melanoma skin cancer. In addition, the prevalence of psoriasis in the world varies from 0.09 percent to 11.43%, making it a serious condition that affects at least 100 million people worldwide. The fact is that topical drug administration is the primary therapy method for most skin conditions, and the market for advanced topical products is projected to grow in the upcoming years.

GOVERNMENT'S ROLE IN PROMOTING GENERIC DRUGS

The Medical Council of India (MCI) introduced an amendment to the Indian Medical Council Regulations (Professional Conduct, Etiquette, and Ethics) under clause 1.5 in September 2019 which states, 'that 'every physician should, as far as possible, prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs. This was followed by a statement made by the honourable Prime minister of India on 17th April 2017 regarding the framing of a law to make it mandatory for doctors to prescribe medicines by their generic names. In this regard, another circular dated 22nd April 2017 was released by the MCI that stated provision for disciplinary action against defaulters. This gave a new momentum to the utilisation and availability of generic drugs in the country.

In order to promote the utilisation and promotion of Generic drugs, in September 2015, the *'Jan Aushadhi Scheme'* (2008) was revamped as 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY). In November 2016, to give further impetus to the scheme, it was again renamed as

"*Pradhan Mantri Bhartiya Janaushadhi Pariyojana"* (PMBJP)[9]. The aim of this scheme was to establish dedicate outlets known as *Jan Aushdhi Kendras* across the country to provide generic medications for all. The scheme aimed to have drugs and located in all the districts of the country extending to sub districts. There are 12616 functional Jan *Aushdhi Kendras* till date and it covers around 2047 drugs and 300 surgical items.

To maintain high quality, medicines for Pradhan Mantri Bhartiya Janaushadhi Kendras are sourced from manufacturers following WHO Good Manufacturing Practices (GMP), Current Good Manufacturing Practice (CGMP), and Central Public Sector Undertakings (CPSUs). Each batch of procured drugs undergoes random testing at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL), ensuring the quality, safety, and efficacy of the medicines meet required standards. Only after certification from these labs are the medicines dispatched to agents, distributors, and Janaushadhi Kendras.

PERCEPTION OF GENERIC MEDICINES IN INDIA

Time and again several studies have been conducted in different parts of the country in assessing the knowledge attitude and practices of the health care providers in the field of generic medicine. Such studies were conducted in Jammu, Tamil Nadu and Maharashtra to understand the prescribing patterns and the acceptance of the doctors in promoting the use of generic medicines. There are peculiar similarities in the findings of these studies. A good proportion of doctors (>75%) have a positive attitude[10] towards the safety, efficacy and quality of generic medicines, and majority of them said that they prescribe generic drugs. However, concerns with the bioequivalence, dosage, effectiveness are still prevalent. Another striking finding was a major difference in the knowledge of doctors and their prescribing patterns [11]for the generic drugs. Further work is needed on how interventions for medical professionals and for the public can lead to increase in the awareness and acceptability of generic medicines.[12]

The study on the doctors of Odisha however had adverse results. Doctors often provided misinformation regarding the wellbeing, effectiveness, and reliability of generic medications. Odisha doctors, overall, have poor preferences and views towards generic and locally made drugs. Doctors among higher expertise had a somewhat unfavourable impression and opinion concerning the efficacy and safety of the locally manufactured generic drug in India[13].

In India, and similar developing countries, private community pharmacies are the main source of medicines, and dispensing is mainly undertaken by pharmacists and drug retailers or sellers.

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[9] https://janaushadhi.gov.in/pmjy.aspx
[10] https://www.njppp.com/index.php?mno=164132
[11] http://www.jcmad.com/admin/pdf/326.pdf
[12] https://www.researchgate.net/profile/Pavan-Malhotra-2/publication/324066906_A_study_on_assessment_of_awareness_on_generic_drugs_among_doctors_in_a_tertiary_care_teaching_hospital_in_north_India/links/5bf6898792851c6b27d1eac4/A-study-on-assessment-of-awareness-on-generic-drugs-among-doctors-in-a-tertiary-care-teaching-hospital-in-north-India.pdf
[13] https://www.researchgate.net/profile/Arya-Kumar/publication/366397566_KNOWLEDGE_AND_ATTITUDES_TOWARDS_THE_USE_OF_GENERIC_DRUGS_BY_THE_DOCTORS_OF_ODISHA/links/639fd3a3095a6a77743fc815/KNOWLEDGE-AND-ATTITUDES-TOWARDS-THE-USE-OF-GENERIC-DRUGS-BY-THE-DOCTORS-OF-ODISHA.pdf?origin=journalDetail&_tp=eyJwYWdlIjoiam91cm5hbERldGFpbCJ9

Drug retailers include individuals who are only associated with private pharmacies, but do not have formal training in dispensing medicines and may not have even passed secondary school. Drug retailers are consulted for health advice on illnesses of all kinds, and medicines as remedies are dispensed. Consequently, both the pharmacists and the drug retailers as the medicines dispensers will have a definite role in improving the quality use of generic medicines.[14] According to a study conducted in Tamil Nadu, to assess the knowledge and practices of drug retailers and pharmacists it was found that a significant number of community pharmacists and drug retailers were unaware of what generic medicines are and their role in improving access to medicines for the Indian population. Many respondents were not entirely convinced that generic medicines are equivalent to branded ones and remained disconnected from the idea of using generics as cost-effective alternatives to brand-name products to help lower healthcare costs. Another concern was the lack of interest among drug retailers in substituting branded medicines with cheaper generic options. Thereby denying the patients the benefits of cost-effective appropriate treatment and access affordable medicines. Negative attitudes toward generic medicines among drug retailers may stem from a lack of knowledge about these drugs, as well as their preference for dispensing branded medicines that offer higher profits or incentive payments. This study promotes a need for educating drug retailers about generic medicines, along with providing sufficient support systems to ensure their appropriate, affordable, safe, and effective use.

HOW TO INCREASE THE USE OF GENERIC MEDICINES IN INDIA:

A) Focus on the pharmacies and drug retailers

In an attempt to struggle with the escalating medicine cost in India, generic substitution could be a solution to the population living below poverty level. Since the pharmacists and retailers are the prime distributors of medicines in the country, a focus on enhancing their knowledge and understanding of Generic drugs can be useful.

B) Strengthening of existing Policies in the country

The availability of drugs and quality of generic medicines remains a concern in the Jan Aushdhi Kendras. Most of the JAK are either not equipped with all the essential drugs or are not completely functional especially in the remote areas and difficult terrains. Strengthening of these dispensing units and most importantly the availability of medicines from the Essential Drug List should be promoted and ensured across the country.

To maximize the contribution of generic medicines to the affordability and sustainability of the healthcare system, the generic medicines industry must be able to operate within a sustainable, competitive and efficient market model. In order to derive the maximum benefit from a generic medicine it must be available from day one following patent expiry[15]

C) Doctors should be encouraged to prescribe more generic drugs

Even after strong advocacy by the government to prescribe and provide generic drugs the ground condition remains questionable. There is no follow up or surveillance of the prescribing

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3687929/#ref7
[15] https://www.aeseg.es/Generic_Medicines_GA.pdf

patterns of the private practitioners largely due to unregulated private health sector in the country. This leads to extensive prescription of branded medicines, often the costliest available in the market leading to a burning hole in the pocket of the care seeker, pushing them towards poverty or forcing them to stop the treatment mid-way. Stricter implementation of the norms should be ensured.

D) Ensuring Quality of Generic Drugs

The use of generic medicines remains suboptimal due to ongoing concerns among physicians and patients regarding their quality. Generic drugs are often perceived as being less effective and less safe compared to their branded counterparts. As a result, brand-name medicines are frequently prescribed, even when more cost-effective generic alternatives are available. One key reason for this preference is the lack of confidence among physicians in the quality of generic medicines. Lack of good manufacturing practices (GMPs) and bioequivalence are the major setbacks for the generic medicine industry.

E) Promotion and awareness about generic medicines

A positive approach towards the utilisation is the need of the hour. How the OOPE can be considerably reduced by the utilisation of generic drugs is something people are still not aware of and this is additionally fuelled by negative reviews by the stakeholders of medicines and healthcare. This aspect should not be looked upon and more emphasis should be laid on positive aspects of generic medicines and their use in the long run.

CHALLENGES IN THE UTILISATION OF GENERIC MEDICINES

There are various regulatory norms that ensure the quality of the Generic drug being manufactured in the The World Trade Organizations (WTO), Trade Related Aspect of Intellectual Property Rights (TRIPS) and FDA regulations often make it difficult for the manufacturers to comply with the guidelines and often a lot of time and effort are invested in this direction leading to unnecessary delays and wastage of energy, both physical and monetary.

While the developing countries are battling to implement TRIPS and taking measures for cost cutting in healthcare sector, a wave of bilateral international agreements has emerged called Free Trade Agreements (FTAs). The common feature to almost all the FTAs signed or negotiated across the world is the inclusion of many TRIPS plus provisions which provided enhanced intellectual protection to the pharmaceuticals. This is completely contrary to the concept of non-proprietary medication that the pharmaceuticals need in the generic drug category.

Another challenge is the hindrance caused by the big pharma companies to ensure regularised flow of income from their drugs even after the patent is expired. These companies have started the pattern of creation of a “patent cluster’’ and protecting the medicines by numerous patents or patent pending leading to lack of transparency in the generic medicine sector.

Marketing of the branded drugs has also created a negative outlook for the generic medicines available in the market. Along with this the biggest issue is the standardisation and quality assurance in the available generic drugs in the market. This is a major concern that affects the utilisation of generic medicines.

CONCLUSION

Generic drugs are the future of tomorrow and the best solution to the rising health care expenditures across the world. With many drugs reaching the stage of patent expiry, the market for these drugs has grown immensely and shows a promising approach in achieving Universal Health Coverage. There are concerns of Quality and effectiveness of the generic medicines available in the market but these can be easily overcome by strict laws and adherence of the manufacturers to the conditions proscribed for drug development. India stands at a position where there is immense potential for this genre of medicines and can prove to be beneficial for the population in the long run.