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Jan Aushadi Scheme: A Crucial Step towards Achieving Health Equity

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1. INTRODUCTION

Health Equity is a widely acknowledged policy objective for all responsible governments around the world. Equity refers to "equal access to available care for equal need, equal utilization for equal need, and equal quality of care for all" (*Whitehead, 1992*). Simply put, Health Equity is about ensuring that every person has the chance to be as healthy as possible. In this context, access to affordable medicines becomes a crucial component towards attaining equity, as even today, drugs constitute a high proportion of out-of-pocket (OOP) expenses, often causing untold financial hardships for most households.

Ever since the acceptance of modern medicine as a scientific and reliable mode of treatment, the use of medications to treat diseases has been increasing worldwide.

Healthcare costs are the second most frequent reason for rural indebtedness in India. A significant component of this healthcare cost is medicines. According to Planning Commission estimates, the cost of medication in India ranges from 50% to 80% of the total cost of treatment. Since 80% of outpatient care and 60% of in-patient (hospitalization) care occurs at private facilities, households are exposed to the private sector to buy medicines *(Sharma, 2015). Saksena, et al. (2010)* has thus referred to such out-of-pocket expenses as catastrophic expenditure as they are a significant reason for pushing low and middle-income households into poverty.

An ideal solution would be to distribute medicines free of cost; however, its financial feasibility is highly doubtful, especially when the Indian government spends just over 1.5% of the gross domestic product (GDP) on healthcare. Besides, neo-liberal policies call for the reduced role of the state in healthcare. In such a situation, where the government is financially constrained, and the patient cannot avoid private healthcare services, the appropriate option to decrease the patient's OOP expenditure is through generic medicines.

Many countries have adopted policies in favor of generic medicines. In this context, the "Jan Aushadi (People's Medicine) Scheme" (JAS) was launched by the Government of India in 2008 to make low-priced quality medicines available for all through dedicated stores.

Objectives of the Study

This paper aims to highlight the vital role of generic medicine in healthcare systems and the need to establish generic medicine policies. It also intends to understand some of the major

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issues plaguing the Indian Generics Campaign – 'Jan Aushadi' and plausible solutions to overcome the same.
While doing so, the paper also tries to discuss the experiences of countries in the implementation of their generic medicine policies. Accordingly, the main facilitators and barriers to generic substitution are identified and presented as recommendations that could be implemented to improve the use of generics, thus furthering the cause of health equity in the country.

2. METHODOLOGY

This descriptive review was based on an extensive literature search using several electronic databases and search engines, including PubMed, Scopus, Science Direct, Libgen, Springer Link, Google Scholar, and Google. Additionally, peer-reviewed research papers were studied to understand the present state of research and findings in generic medicine adoption and public policy. Websites of several health organizations and agencies, including regulatory authorities, were visited for relevant information and reports.

Literature Review

The Sustainable Development Goals (SDGs) adopted by the United Nations (U.N.) form the core of Agenda 2030 and constitute the roadmap to achieve a better and more sustainable future for all. Access to affordable and quality medicines forms part of the 8th target under Goal 3: 'Good health and well-being. The development and adoption of Generic drugs can develop a crucial strategy to achieve this commitment.

What are Generics?

A generic medicine is defined by the World Health Organisation (WHO) 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" *(WHO, 2016).* Approval of generic medicine is based on the demonstration of therapeutic equivalence to the innovator through bioequivalence studies. Bioequivalence is the absence of a significant difference in the rate and extent to which the active pharmaceutical ingredient (API) in pharmaceutical equivalents becomes available at the site of drug action when administered in the same dose *(WHO, 2016).*
A generic medicine is identical to its corresponding innovator medicine in terms of safety, quality, efficacy, dosage form, strength, and route of administration. It has the same intended use as the innovator medicine. The active ingredients are the same, but the excipients (inactive ingredients) might differ from one product to the other *(The U.S. Food and Drug Administration, 2017).*

Role of generic medicines in the healthcare

Drug research and development is an expensive process and takes many years. Clinical trials to ensure drug safety and efficacy for patients also adds considerable time and costs to branded products. Generics do not go through this cycle, and it cost a lot cheaper and takes less time for development than first-time branded drugs. The generic drug manufacturer invests primarily only in the production and distribution of the drugs in the market. Hence, they can sell generic medicines at lesser prices compared to their counterparts. Another primary reason for the high costs of branded medicines is the costs of marketing and advertising. Vast sums of money are spent on marketing new medications to patients/consumers, and doctors. Pharmaceutical companies need to invest in channels whose primary members are the sales

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team, with medical representatives as their foot soldiers who visit the doctors and promote the drugs. For generic manufacturers, as the drug has already been in the market and the generic formulations are well known to patients and healthcare providers, they don't need to spend much on advertising and marketing efforts.

Accounting for these reasons, the *Cameron, et al. (2012)* study calculated that generic drugs might cost 9% - 89% lower than branded equivalents.

In addition to this direct impact, generics also play a crucial role in lowering the prices of off-patent innovator medicines and other generic equivalents to be competitive in the market. A study in Sweden found that the introduction of the mandatory generic substitution policy resulted in a 15% reduction in overall medicine prices and more than 40% decrease in off-patent medicine prices within four years of the policy implementation *(Pharmaceutical Benefits Board (LFN), 2007)*. Similar results were found by *Aalto-Setata (2007)* in Finland, where there was a 10.6% reduction in prices of medicines and up to 80% price decrease in some medication during the first year of implementation of generic substitution policy.

Considering the growing pressure on Governments to increase healthcare spending, generic medicine procurement offers substantial saving and better resources utilization to improve health outcomes. Switching to generic medicine procurement from innovator brands in 17 developing countries resulted in average cost savings of 60% *(Cameron, et al., 2012)*. Hence successful implementation of generic substitution policy and increasing the availability of generic medicines play a substantial role towards improving the affordability of healthcare for not only patients but also Governments.

Jan Aushadi Scheme

India is one of the leading countries to export world-class generic medicines and make one out of six drugs globally. Yet, only 40% of its population can afford branded pharmaceutical medicines whose market is $41 billion *(Economic Survey of India, 2021)*. The Jan Aushadi scheme was designed to bridge this dichotomy and bring world-class medication to the rest of the 60%.

Since its launch by the Department of Pharmaceuticals in 2008, a total of 8020+ outlets (Jan Aushadi Kendras/Stores- JAKs) are functional across the country, providing quality medicines at an affordable price to every citizen, irrespective of their caste, creed, and economic stratification *(Pharmaceuticals and Medical Devices Bureau of India (PMBI), 2021)*. The scheme enables substantial savings in healthcare expenditure, particularly for economically poor and patients suffering from chronic diseases. The Bureau of Pharma Sector Undertakings (BPSU) of India, a special wing of Department of Pharmaceuticals, is Pradhan Mantri Bhartiya Jan Aushadi Pari Yojana (PMBJP). The product basket of this scheme covers more than 800 medicines spanning a wide range of infectious diseases, NCDs (cardiovascular diseases, diabetes), mental health disorders (anxiety), analgesics, vitamins, supplements, and tetanus toxoid injections. These drugs are specially procured by floating tenders from companies with WHO cGMP compliant plants at the main level after performing adequate quality checks performed by the National Accreditation Board for Testing and Calibration Laboratories. Drugs are then dispensed to distributors in the various states, who supply them to JAK retailers (franchise model, fixed 20% margin) as per their requirements. In addition, Assistance of Rs.2 Lakhs to 50 lakhs is provided as incentives for store owners. The JAKs can be opened by non-governmental organizations (NGOs), charitable institutions, private hospitals, registered professional organizations, or self-help groups (SHGs).

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The first Pradhan Mantri Jan Aushadi Kendra was opened on 25th November 2008 at Amritsar in Punjab. In its first decade, the growth of such stores was found to be very slow, with BPSU reporting having opened 164 stores, out of which only 87 were found to be functional. The pace picked up, especially since the F.Y. 2016-17, with increased government impetus. However, the scheme is still plagued by significant constraints such as poor supply chain, information asymmetry, lack of awareness in public, doctors not prescribing generic medicines, and inadequate policy support; thus, hindering the realization of the scheme's true potential.
The following sections discuss some of these constraints and suggestions to overcome the same while drawing comparisons from international experience of implementing generic medicine policies.

3. DISCUSSION

Medicines play a vital role in protecting and maintaining the health of populations. Thus, providing adequate quality treatments at reasonable prices and sufficient quantities should focus on national policymakers and agencies implementing health programs. The Jan Aushadi Scheme is a policy initiative in this direction.
Srivatsa, et al. (2020) studied the customer's buying behavior of generic medicines and enlisted trust, availability, and lower prices as the most important variables influencing the adoption of generics.
'Trust' is a function of many factors – the quality of generics, patient's drug literacy, doctor prescriptions, and word-of-mouth. There have been many studies undertaken to prove the quality of generics and their bioequivalence with branded drugs. *Singhal, et al. (2011)* compared the quality of four generic drugs (alprazolam, ciprofloxacin, cetirizine, and fluoxetine), while *Singh, et al. (2016)* compared the rate of antidiabetic drug metformin and both studies found the generic versions to be of good quality as that of their branded counterparts. *Tank, et al. (2016)* tested ceftazidime in JAS and demonstrated no difference in in-vitro anti-microbial activity to the branded drugs. Thus, the quality aspect of generics has come to be firmly established in scientific quarters.
However, prescribing generic drugs is still not a common practice among physicians in India. Even in government hospitals, prescriptions are written by brand name. Even though there is widespread knowledge and overall positive opinion about generics among doctors *(Gupta et al., 2015)*, the percentage of generic prescriptions is abysmally low. Some studies reporting less generic prescriptions are (% of generic prescriptions mentioned in brackets) – *Shamna et al., 2011* (0%), *Bathini, et al., 2015* (4.83%), *Shelat et al., 2015* (6.67%), *Satpathy et al., 2016* (11%), and *Mahajan et al., 2010* (15%). A significant reason for this is the cozy connection between doctors and pharmaceutical companies which influence prescription practices. There is compelling evidence that pharmaceutical companies sponsor conferences and offer other inducements that make the glitter of the branded drug industry too irresistible for medical practitioners. The Medical Council of India had issued regulations (for Professional Conduct, Etiquette and Ethics, 2002) that all physicians prescribe drugs with generic names. However, strict implementation of these rules is found wanting.
As a result of this situation, the onus for promoting generic drugs falls on the pharmacists through generic substitution. However, the study conducted by *Rawat, et al. (2016)* found nearly 50% of the pharmacists are unaware of the Jan Aushadi Scheme itself. A majority who are aware of the scheme are not opting for dispensing generic medicines as it involves

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economic loss. Expired pharmaceutical companies replace branded drugs. In contrast, the pharmacies' generic medications are not returned, and it becomes the pharmacist's responsibility to dispose of the expired generic stock. Moreover, the branded medicines provide hefty margins for the retailers – in the range of 201% - 1016% *(Singal, et al., 2011)* for branded generic pharmaceuticals. All these supply-side constraints result in a low rate of prescriptions with generic formulations.

All countries that have successfully adopted generic medicine policies have achieved the same through increased generic prescriptions as one of the main strategies. About 80% of prescriptions filled are generic medicines *(US FDA, 2012).* The United Kingdom (U.K.), in 2008, had more than 83% of prescriptions written with generic names (*Department of Health, 2009*). A noteworthy difference in the generic policy is that, unlike the U.S. that allows generic substitution by pharmacists, the U.K. disallows generic prescription and has gone for mandatory generic prescribing by medical practitioners. Thus, pharmacists have to dispense the prescribed brand mandatorily. This difference only points to the fact that generic prescription can be increased with strict focus and policy implementation, generic substitution, or generic prescribing irrespective.

Generics are envisaged as a cheaper therapeutic alternative to high-priced branded drugs. However, not all generic medicine prices are lower than branded medicines in Jan Aushadi Stores. The study conducted by *Mukherjee (2017)* brings out the case of antibiotic cefuroxime axetil, where cheaper varieties are available in branded markets than JAS. Such cases fail the very purpose of the scheme as it leads to an increase in OOP expenditure of patients and undermines the efforts to create awareness about generics.

Availability of generic equivalents and their accessibility through Jan Aushadi Kendras (JAKs) plays a pivotal role in establishing market-share of generics and shaping positive customer perception, thus bolstering the promotion efforts through word-of-mouth. However, the scheme's challenge is making a more extensive range of products available at all times for a majority of the diseases.

Recommendations to improve generic medicine use

To effectively promote generic medicine use in the country, it is evident that the central policy of the Jan Aushadi Scheme needs to be supported by complementary policies and initiatives to overcome the significant barriers and facilitate its implementation. To this outcome, keeping in line with the discussion above, the paper provides recommendations on improving four target determinants – Trust, Value, Convenience, and Policy reform.

Education levels on generics are low among India's public and health professionals *(Mani, et al., 2017).* Lack of campaigning and awareness about the Jan Aushadi Scheme hampers the implementation, as it exudes lesser faith among the public. *Fraeyman, et al. (2015)* studied the consumer's perception of generic medicines in Belgium. The study found a strong positive correlation between generic medications and consumers' knowledge of generic formulations. Hence scaling up of marketing efforts among media, educational, and awareness programs with the involvement of civil society are required on a war footing. An independent not-for-profit organization, National Prescribing Service Limited (NPS), has been set up in Australia, whose primary responsibility is to educate consumers about generics medicines and brand choices. It also organizes educational campaigns and materials *(National Prescribing Service Limited (NPS), 2021).* Such an organization can be envisaged even in the Indian scenario, probably under the aegis of the Bureau of Pharma Sector Undertaking (BPSU).

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Quality is the most critical determinant in forming a positive attitude towards generics *(Patidar, et al., 2019)* by all stakeholders – Medical Practitioners, Healthcare Professionals, Pharmacists, and Patients. Although many studies have established the quality, safety, efficacy, and bioequivalence of generic medicines, drug regulatory authorities should ensure that only quality products are available in the market, as even one instance of low quality or counterfeit medicines could undermine the entire promotional efforts of generic and result in loss of confidence in the whole healthcare system.

Strong supply-side regulation is the need of the hour to prevent widespread prescription of costly branded medicines. The Medical Council of India has issued a regulation (*for Professional Conduct, Etiquette and Ethics, 2002*) that every physician should prescribe generic names of drugs. Adherence to this should be ensured through mechanisms such as prescription and compliance audits, imposition of penalties, etc. This is imperative as it has related domino effects of increasing awareness, trust, and acceptability of generics usage among the public. In addition, Physicians should be empowered with technology and decision support systems to help them with generic prescription and cost-effective options. A generic prescribing program can be proposed to this effect.

For retailers to find value in stocking and dispensing generics, various profit-sharing models have to be explored. Measures such as Government subsidy on generics, incentives for generic substitution, near-expiry generic replacements, price control of branded drugs etc., could be employed to encourage active participation of pharmacists in JAS.

Convenience is an important ingredient for successful implementation for any governmental programme. This translates into easy accessibility of Jan Aushadi Stores/Kendras and all-time availability of wide range of generic alternatives in these outlets. Towards the former, presently all medical stores in government hospitals could be converted to (JAKs). This may even bring uniformity among JAKs. Outlets could also be opened in every pharmacy institute, as this not only increases coverage but also exposes pharmacy students studying in the institutes to the Jan Aushadi Scheme.

Availability of generics in all pharmacies should be ensured through strong supply chain. Prime shelf-space should be provided in these pharmacies with attractive packaging to increase visibility. Home delivery, e-pharmacy, mobile vans, tele-medicine and various IT applications could be explored to increase the convenience quotient of generics use.

4. CONCLUSIONS

Generic medicines can provide substantial savings to overall healthcare systems. However, there are many challenges in the implementation of the Jan Aushadi Scheme, each of which needs to be tackled in a wholistic manner, understanding the concerns of all the stakeholders - government agencies, pharmaceutical companies, pharma retailers and patients. Only then a sustainable adoption of generics can be achieved and thus furthering the cause of health equity in the country.

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