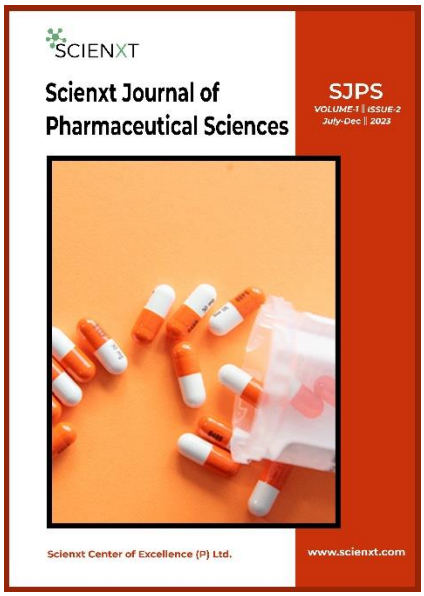

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Prescribing by generic name: pros and cons

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Abstract:

The National Medical Commission (NMC) has issued new regulations that require all doctors to prescribe generic medications. If they do not, they will be penalized and their license to practice medicine may be suspended temporarily, according to news that was reported in The Times of India on August 13, 2023. In its "Regulations relating to Professional Conduct of Registered Medical Practitioners," the NMC urged physicians to abstain from providing name-brand generic medications. In addition to offering an analysis of the news, the article seeks to identify the justifications, benefits, and drawbacks of this regulation. The entry of generic medicines in market brought a revolutionary change in healthcare system and the market share is continuously increasing. Because these are genuine, trustworthy, safe, affordable, and available to everyone, the society's poor and needy groups benefit. Now there is an option available against the high-cost branded medicines. The Indian government is doing a lot to increase access to generic medications in both urban and rural areas, as well as to raise awareness among the public that these medications are just as effective and safe as name-brand medications. Generic medications are produced by numerous pharmaceutical companies and distributed to consumers through retail establishments. Generic medications can now be delivered to your home by e-pharmacies. Throughout the nation, the government has opened thousands of Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK), where people can purchase generic medications for a significantly reduced price. The research used to create this article included a look at where generic medications can be obtained outside of PMBJK, a price comparison of generic and branded medications, and an analysis of the factors that contribute to generic medications' lower cost.

Keywords:

Generic medicines; Pradhan Mantri Bhartiya Janaushadhi Pariyojna PMBJP; Pradhan Mantri Bhartiya Janaushadhi Kendra PMBJK; Price comparison, branded medicines; Market share, medicines in India

1. Introduction:

1.1. Pharmaceutical sector:

The Indian pharmaceutical sector has gained international recognition for its production of generic medications and affordable vaccinations. Over the course of time, the Indian pharmaceutical industry has undergone significant changes and has emerged as a thriving sector. Currently, it holds the third position globally in terms of pharmaceutical production volume. Over the course of the past nine years, the Indian pharmaceutical sector has exhibited consistent growth, as seen by a Compound Annual Growth Rate (CAGR) of 9.43%. The pharmaceutical sector has continuously generated a trade surplus. In the fiscal year 2020-21, the pharmaceutical industry witnessed a total export value of ₹180,555 crore, while the total import value of pharmaceutical products amounted to ₹49,436 crore. Consequently, this resulted in a trade surplus of ₹146,991 crore in the pharmaceutical sector. As of the conclusion of September 2021, the cumulative value of pharmaceutical exports amounted to ₹ 87864 crore, while the entire value of pharmaceutical imports reached ₹ 33636 crore. Consequently, this resulted in a trade surplus of ₹ 54228 crore. The Indian Pharmaceutical Industry encompasses several significant sectors, namely generic drugs, over-the-counter (OTC) medications, bulk drugs, vaccines, contract research and manufacture, biosimilars, and biologics. The Indian pharmaceutical business holds considerable prominence on a global scale. India boasts the largest number of pharmaceutical factories outside of the United States of America that are compatible with the regulations set forth by the United States Food and Drug Administration (USFDA). The global API industry is comprised of approximately 500 producers, collectively accounting for an 8% contribution. India holds the distinction of being the foremost provider of generic medications, commanding a significant 20% portion of the worldwide supply. This achievement is realized through the production of an extensive range of 60,000 distinct generic brands, spanning across 60 therapeutic classifications. The provision of cost-effective HIV therapy from India stands as a remarkable achievement within the field of medicine. India is widely recognised as a prominent global provider of affordable vaccinations. The global preference for Indian pharmaceuticals can be attributed to their competitive pricing and superior quality, which has earned India the reputation of being the "Pharmacy of the world". The Indian pharmaceutical industry has significantly contributed to addressing the issues associated with mitigating the infection during the COVID-19 pandemic. The industry engaged in extensive collaboration with governmental bodies and academic institutions to expedite the development and enhancement of manufacturing processes. These efforts were instrumental in

guaranteeing a reliable provision of essential medications for the treatment and control of COVID-19, such as Remdesivir, Ivermectin, Hydroxychloroquine, Dexamethasone, Tocilizumab, and Favipiravir, among others. During the COVID-19 pandemic, India has supplied Hydroxychloroquine (HCQ) to more than 120 countries, paracetamol to 20 countries, and vaccinations to around 96 countries, thereby offering relief to these nations. Year wise growth rate from 2015-16 to 2020-2021is given in Fig 1.

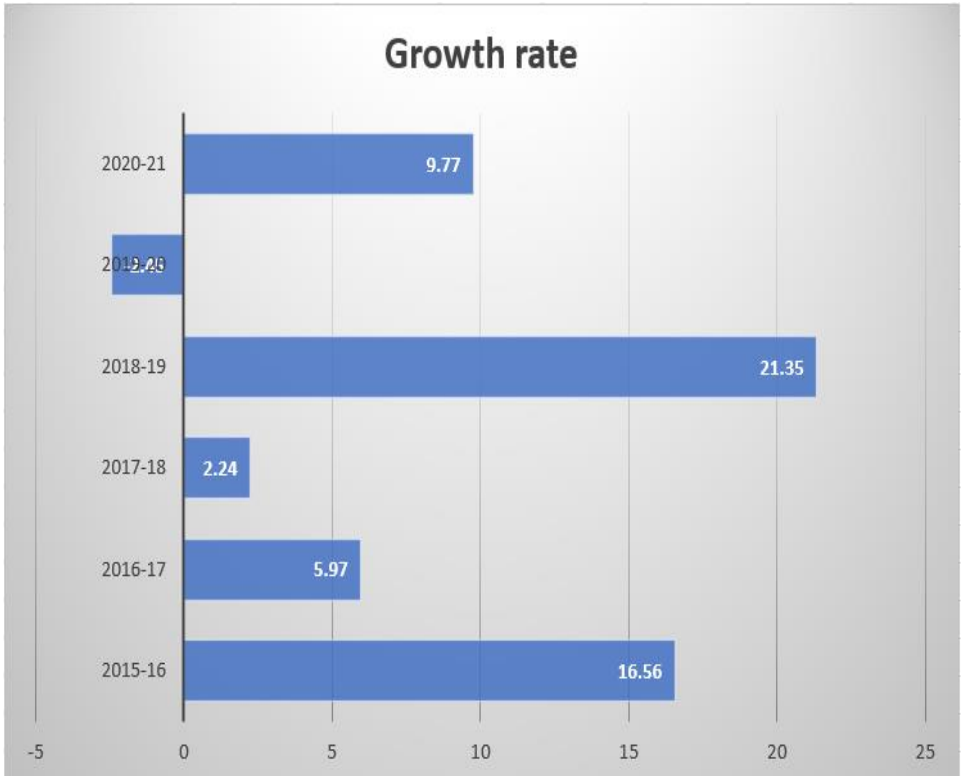

Figure. 1: Shows year wise growth rate from 2015-16 to 2020-2021

Table. 1: Shows the year wise growth of pharmaceutical sector

Year	**Output in crores**	**Growth rate**
2015-16	3,03,352	16.56
2016-17	3,21,472	5.97
2017-18	3,28,677	2.24
2018-19	3,98,852	21.35
2019-20	3,89,094	-2.45
2020-21	4,27,109	9.77

1.2. Major credentials of the pharma industry:

1. India exports generic pharmaceuticals to more than 200 countries throughout the world.
2. India is home to eight of the top twenty generic businesses operating worldwide.
3. More than 55 percent of sales are made in highly regulated markets.
4. India is the primary country of origin for ninety percent of all WHO Pre-Qualified APIs.
5. India provides between 65 and 70 percent of the vaccines that the WHO needs.
6. The total number of sites that have been granted approval by the FDA is 741 as of August 2021.
7. According to the data available as of December 2020, Indian firms have obtained a total of 4,346 market authorizations for Abbreviated New Drug Applications (ANDAs).

1.3. The National Medical Commission (NMC) regulations:

According to the newly released regulations by the NMC, it is mandatory for all physicians to prescribe generic medications. Failure to comply with this requirement may result in penalties and the suspension of their medical licence. According to the 'Regulations related to Professional Conduct of Registered Medical Practitioners' issued by the NMC, physicians are advised to refrain from prescribing branded generic medications. Although the extant laws released by the Indian Medical Council in 2002 mandate doctors to exclusively prescribe generic pharmaceuticals, there is a notable absence of criminal sanctions within such regulations.

1.4. Definition of branded medicines and generic drugs as per NMC:

The NMC defined generic medicines as a "drug product that is comparable to brand/reference listed product in dosage form, strength, route of administration, quality and performance characteristics, and intended use". A branded generic drug is one which has come off patent, is manufactured by drug companies and sold under different companies' brand names.

1.5. Definition of generic drug as per WHO:

According to the definition given by the World Health Organization (WHO), generic medicines or generics are pharmaceutical products usually intended to be interchangeable with the innovator product, marketed when period of patent is over or other exclusivity rights.

1.6. Generic medicines or generics:

Generic pharmaceuticals are seen as a beneficial option for those who often overlook the potential health risks due to the exorbitant prices associated with branded medications. This

phenomenon is playing a significant role in enhancing the healthcare system of the nation. The Indian populace encounters challenges when faced with the decision of selecting between branded and non-branded merchandise. In contrast, it is worth noting that in Western countries, there exists a clear distinction between these two categories due to the well-established idea of generic drugs. The United States accounted for around 89% of all prescriptions filled using generic medications, while India is currently in an emerging phase. The Drugs & Cosmetics Act, 1940 and Rules, 1945 do not provide a clear definition for generic or branded drugs. Generic drugs are defined as medications that contain the identical active ingredient(s) in the same dosage form, taken via the same method of administration, and possess equal safety and efficacy as branded medicines. The introduction and proliferation of generic medications in the market have proven to be a favourable development for patients, particularly those who are economically disadvantaged. Additionally, medical institutions and governmental bodies, including states and union territories, have also benefited from this trend. Conversely, makers of branded medicines have seen adverse effects as a result.

In order to mitigate pharmaceutical expenditures, it is imperative to foster research endeavors aimed at discovering novel generic medications, life-saving drugs, and critical pharmaceuticals as alternatives to costly branded medications. This will prove beneficial for individuals with little financial means. The global pandemic caused by COVID-19 has resulted in widespread financial challenges that have been experienced by individuals and communities alike. The affordability of low-cost generic pharmaceuticals enables individuals to effectively combat pandemic-like circumstances by providing access to these medications at a reasonable price. Furthermore, it is worth noting that the cost of certain generic medications is rather expensive. In light of this, it is imperative for the government to implement measures aimed at reducing these prices. It is advisable for the government to actively encourage the expansion of enterprises such as Davaindia in both urban and rural areas.

1.7. Quality of generic medicines:

The Drugs and Cosmetics Act of 1940 and the Rules of 1945 stipulate that any pharmaceutical product manufactured in the country, regardless of whether it is branded or generic, must satisfy the same quality and performance requirements in order to be considered compliant with the law. It is anticipated that both will have outcomes that are comparable.

1.7.1. The advantages of generic medicines:

According to the regulations issued by the NMC on August 13, 2023, it has been observed that a significant amount of India's healthcare expenditure is attributed to out-of-pocket expenses on drugs.

- Generic medications are typically priced at a significantly lower cost, ranging from 30% to 80% less expensive than their branded counterparts.
- the utilization of generic medications in medical prescriptions has the potential to significantly reduce healthcare expenditures and enhance the availability of high-quality healthcare services.
- Generic drugs are often regarded as being both effective and safe, comparable to their branded counterparts.
- both generic and branded pharmaceuticals are subject to the same regulatory oversight and must comply with identical quality standards.
- once the patent period of branded pharmaceuticals has expired, they enter the public domain, thereby allowing any entity to produce their generic counterparts.
- Pharmaceutical businesses are under pressure to lower their branded prices due to lower generic prices and increased competition.

1.7.2. Reasons of the lower price of generic medicines:

If everything is the same, why are branded drugs more expensive than generics? A generic drug is usually cheaper than a branded one because of following reasons. First, the pharmaceutical business saves money by not advertising its product. The pharmaceutical industry's motive for the selling of generic medications is to maintain a strong trading margin for wholesalers and retailers. Secondly, after the successful creation of a novel molecule, pharmaceutical companies proceed to pursue a patent for that molecule. Obtaining a patent entails exclusive rights for a duration of 20 years, during which no other pharmaceutical business is permitted to produce the patented product. The chemical is sold at a higher price following its formulation due to the exclusive manufacturing rights held by the seller. Once a patent reaches the 20-year mark, it expires, so placing the formula into the public domain. Consequently, other pharmaceutical businesses get the ability to produce the same product. In the event that multiple companies engage in manufacturing the identical product, market competition ensues, resulting in a subsequent decrease in price.

1.8. Comparison of price of Generic Vs Branded medicines:

Here are many examples that elucidate the disparity in pricing between generic and brand-name medications. The study compared the prices of generic drugs from the PMBJAK with those of well-known pharmaceutical businesses.

Table. 2: PMBJAK Generic Vs Branded: Price comparison

S.NO.	Product	Price/Quantity	
		Generic PMBJK	Branded
Analgesic/Antipyretic/Anti-inflammatory			
1	Ibuprofen tablets IP 400 mg	08.00/15	16.60/15 (Brufen 400 by *Abbott)
2	Paracetamol tablets IP 650 mg	15.00/15	28.46/15 (Calpol 650 Plus by *Glaxo smithkline)
Anti-histaminic			
4	Cetrezine hydrochloride IP 10 mg	05.00/10	15.70/10 (Okacet by *Cipla)
Oncology			
5	Capecitabine tablets IP 500 mg	250.00/10	678.77/10 (Capegard 500 by *Cipla)
Antibiotic			
6	Azithromycin tablets IP 500 mg	42.00/03	67.23/03 (Azicip 500 by *Cipla)
7	Clarithromycin tablets IP 500 mg	72.00/04	134.26/06 (Clarinova 500 by *Mankind)
Central Nervous System (CNS) Acting			
8	Citicoline tablets IP 500 mg	221.00/10	639.20/10 (Somazina 500 mg by *DR. Reddy's)
Cardiovascular system (CVS) Acting			
10	Enoxaparin injection IP 60 mg/ 0.6 ml	217.80/0.6 ml	399.50/40 mg-0.4 ml (Enoxarin-40 Inj. 0.4 ml by *Zuventus)

12	Aspirin Gastro resistant tablets IP 150 mg	05.00/14	09.00/14 (Ecosprin-150 by *USV)
Steroids and hormones			
13	Methylprednisolone sodium succinate inj. 1000 mg/vial	317.00/vial	987.70/500 mg-04 ml vial (Solu-Medrol 500 mg Injection 4 ml by *Pfizer)
Eye/Otic			
14	Nepafenac 0.1% w/v eye drop	66.00/5 ml	359.00/5 ml (Nevanac Ophthalmic Suspension by *Alcon Laboratories)
GIT			
16	Ursodeoxycholic acid tablets IP 300 mg	160.60/10	649.00/15 (Udiliv 300 by *Abbott)
Topical/Local antiseptic/disinfectant			
18	Povidone iodine 5% w/v solution 100 ml	21.00/100 ml	46.00/100 ml (Mutadine 5% Solution by *Multicure)
Respiratory Tract Drugs Acting On Urogenital Organs			
19	Sildenafil tablets IP 100 mg	10.00/04	123.30/04 (Stimulo 100 *Aauspharma)
Antidiabetic			
20	Insulin inj. IP 40 IU/ml (Insulin human soluble 30% and isophane 70%)	90.00/10 ml vial	151.40/10 ml (Human Actrapid 40 IU/ml Solution for Injection 10 ml by *Novo nordisk)

1.9. Steps taken by government of india for quality and reach:

The Ministry of Health & Family Welfare, under the Government of India, has implemented a range of regulatory measures in order to enhance and guarantee the quality of generic medications.

- Licensing Authorities will only give out or renew licenses to make drugs for sale or marketing if the drugs have a proper or generic name.

- It is now mandatory to grant license for a drug formulation containing single active ingredient in proper name only, as per the amendment in the Drugs and Cosmetics Rules, 1945.
- According to the provision included in the Rules, 1945, submission of the result of bioequivalence study is mandatory along with the application for grant of manufacturing license in the case of certain drugs.
- As per a provision, Drugs Inspectors of Central Government and State Government can perform joint inspection of manufacturing establishment.

1.10. Increasing market share of generics medicines:

According to the given economic scenario, an increase in the supply of generic pharmaceuticals will result in a decrease in their price, indicating an inverse relationship between supply and price. What is the underlying cause or rationale? There are several factors contributing to the growing market share of generic pharmaceuticals.

- When drug patents expire, the drug enters the public domain and can be manufactured by any pharmaceutical business, increasing supply and decreasing prices.
- Numerous people in need of medical care do not have access to affordable health insurance.
- Because of their approval by authorities such as the FDA, generic versions of branded drugs are widely acknowledged to be just as effective and safe.
- Tighter market conditions for prices.

1.11. Sale of generic drugs in the country:

India possesses a greater number of generic medication manufacturing facilities in comparison to other countries, subsequent to receiving approval from the United States Food and drug Administration (FDA). India has successfully established a globally recognized generic medication manufacturing industry, featuring prominent companies such as Cipla, Ranbaxy, and Reddy's Laboratories. Based on the World Health Organization's reports, almost 50% of the global population is experiencing inadequate access to standardized healthcare services. A significant proportion of the global population, exceeding 95 million individuals, now grapples with poverty. Moreover, approximately 800 million people, including those residing in India, allocate a substantial portion of their household income towards medical expenses, particularly for medications and healthcare expenditures. Currently, India holds a significant role in the

pharmaceutical business. It is well recognized as the leading global provider of generic pharmaceuticals. In terms of volume, it accounts for around 20% of the global supply, meeting more than 50% of the demand for various vaccines worldwide. Additionally, it serves 40% of the generic demand in the United States and contributes to 25% of the total medications consumed in the United Kingdom. India is responsible for the production of about 60,000 generic products across 60 distinct therapeutic categories, encompassing the manufacturing of over 500 distinct Active Pharmaceutical Ingredients (APIs). The exportation of generic medications is a significant strength of India, contributing to the economic empowerment of the nation. The generic medicine sector plays a significant role in prioritizing the provision of authentic, affordable, and accessible medications. The customers/patients are provided with pharmaceutical products that have been approved by the World Health Organization (WHO) and the Food and Drug Administration (FDA). However, they encounter significant challenges in assessing the effectiveness of generic meds compared to branded medications. The pharmaceutical industry aims to raise awareness and provide education to the general public regarding the legitimacy and advantages of generic medications. The awareness of generic drugs among individuals will only be attained by the dissemination of information regarding the benefits associated with these medications. This necessitates the implementation of educational initiatives targeting the general populace, which is a process requiring sustained efforts over an extended period of time. The Indian government has implemented the Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) as a means to encourage the utilization of generic medications. Various segments of society are reaping the benefits of generic medicines nationwide through the Prime Minister's Jan Aushadhi Kendra (PMJK) initiative, resulting in significant cost savings on pharmaceuticals.

2. Pradhan mantri bhartiya janaushadhi pariyojana (PMBJP):

Despite being one of the top suppliers of generic drugs globally, the majority of Indians do not have adequate access to inexpensive medications. Despite having comparable therapeutic benefits, branded generic medications are much more expensive than their unbranded generic counterparts. The ministry of Health and family welfare introduced the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in 2008 with the goal of making high-quality generic medications accessible to everyone at reasonable prices, particularly for the underprivileged and impoverished. Fig. 2 shows the Logo of Pradhan Mantri Bahartiya Janaushadhi Pariyojana (PMBJP), an initiative of Government of India to provide quality and

affordable medicines to all and Fig. 4 shows the Logo of Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK), retail outlets under Pradhan Mantri Bahartiya Janaushadhi Pariyojana (PMBJP) functioning all over India. As part of this programme, special pharmacies known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) are set up across the nation to offer generic medications to the general public. On November 25, 2008, the first Jan Aushadhi Kendra in Amritsar, Punjab, was inaugurated. Only 80 outlets were open as of March 31, 2014, since the plan failed to gain traction. In December 2017, the goal of opening 3000 Kendras was attained. Additionally, the updated goal of 6,000 outlets overall was accomplished in March 2020. 9303 Janaushadhi Kendras are operational as of March 31, 2023. The PMBJP's product line includes 285 surgical supplies and 1800 prescription medications. The product basket of the PMBJP will soon include AYUSH items, specifically 75 Ayurvedic medications. By March 2025, the PMBJP is expected to have opened 10,500 Kendras nationwide and added 2,000 medications and 300 surgical supplies to its product offering. Graph shows the increase in number of PMBJP kendras from 2008-09 to 2021-22 in Fig. 3.

Figure. 2: Logo of Pradhan Mantri Bahartiya Janaushadhi Pariyojana (PMBJP), an initiative of Government of India to provide quality and affordable medicines to all

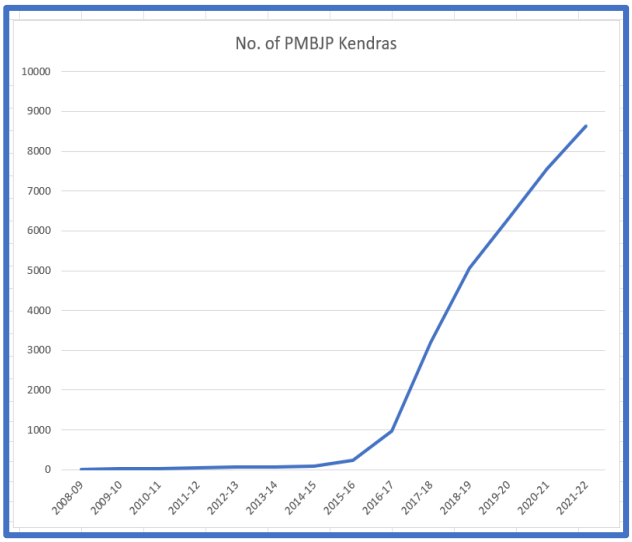

Figure. 3: Graph shows the increase in number of PMBJP Kendras from 2008-09 to 2021-22

Figure. 4: Logo of Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK), retail outlets under Pradhan Mantri Bahartiya Janaushadhi Pariyojana (PMBJP) functioning all over India

Table. 3: Shows increase in number of PMBJP Kendras year wise

Year	No. of PMBJP Kendras
2008-09	04
2009-10	23
2010-11	30
2011-12	46
2012-13	66
2013-14	72
2014-15	86
2015-16	240
2016-17	960
2017-18	3193
2018-19	5056
2019-20	6306
2020-21	7557

2021-22 (As on 31/12/2021)	8640

Antipyretic, analgesic, muscle relaxant, anticancer, anti-infectious, and diuretic medications are all on the market. Drugs affecting the CNS, pharmacological agents affecting the cardiovascular system, pharmacological agents affecting the endocrine glands (including steroids and immunosuppressants), pharmacological agents affecting the ocular and otologic systems, pharmacological agents affecting the respiratory system, pharmacological agents affecting the skin, pharmacological agents affecting the genitourinary system, pharmacological agents affecting diabetes, pharmacological agents Registered chemists with a valid licence and a 10 square metre space can start their own business and earn an income through PMBJAP. You may get the PMBK application at www.janaushadhi.gov.in.

With a large selection of generic medications, Davaindia is a chain of generic pharmacies in India. It is a division of Zota Healthcare, a business that was founded in 1995 with the goal of developing, producing, and marketing pharmaceuticals. More than 616 stores are operating with more than 2000 products (generic medicine, health & wellness, over-the-counter (OTC), cosmetics, protein supplements, gym supplements, nutraceuticals, and surgical products) across more than 25 states in the nation, according to Davaindia's head office in Surat, Gujarat. Fig. 5 shows the logo of Davaindia, a popular name in non-government generic retail chain outlets functioning under Zota Healthcare

Figure. 5: Logo of Davaindia, a popular name in non-government generic retail chain outlets functioning under Zota Healthcare

3. Conclusion:

All doctors must now prescribe generic medications, or face penalties and the suspension of their medical license from the National Medical Council (NMC). It is recommended that prescriptions be written in all capital letters to ensure readability. Errors can be minimized if they are typed and printed. Pros of the rule include the fact that patients will have greater

freedom to choose between more expensive name-brand medications and less expensive generics found through PMBJK if prescriptions are made using the salt name of the drug. The government is persistently working to expand the network of kendras, making its services more accessible to those in need. Cons of the regulation: If a prescription is written by its salt name, a medical store chemist can provide the patient branded, more expensive drugs. Generic versions of all branded drugs are unavailable, and government and private sources for generics are few. In addition to allowing more private enterprises to operate generic medical stores like DavaIndia in both rural and urban regions, the government should improve the variety of generic medicines in his product basket.

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4.1. Disclosure of conflict of interest:

The Authors declares that there is no conflict of interest.

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