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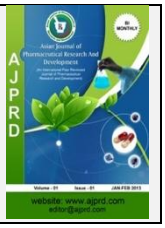

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Review Article

A Review: A Comparative Study of Branded and Generic Anti- Diabetic Drugs

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A B S T R A C T

This comprehensive review investigates the market landscape of antidiabetic medications, undertaking a detailed comparative analysis of branded and generic options. In the face of rising global prevalence of diabetics, the study aims to provide a holistic perspective on the efficacy, safety, and market dynamics shaping the use of branded and generic drugs in the management of these chronic conditions.

Utilizing data derived from market trends, sales analytics, and consumer preferences, the review scrutinizes the market behaviors and forces influencing the adoption of branded and generic antidiabetic drugs. Factors such as cost-effectiveness, patient adherence, and healthcare provider preferences are explored to shed light on the complexities associated with medication selection in the context of chronic disease management.

Through an in-depth examination of industry strategies, regulatory frameworks, and the role of healthcare policies, the review aims to uncover the interplay between market dynamics and clinical considerations. It seeks to inform healthcare professionals, policymakers, and industry stakeholders about the evolving landscape of choices in antidiabetic therapies, fostering a nuanced understanding that can guide optimal decision-making in patient care and resource allocation.

Keywords: Antidiabetic ,Generic Drug, Branded drug

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INTRODUCTION:

The term "generic drug" refers to a medication that shares the same chemical composition as a drug that was first covered by a chemical patent. Following the expiration of the patents on the original medications, generic medications may be sold. The medical profile of generic medications performs similarly to that of their proprietary counterparts since the active chemical ingredient is the same. A generic drug has the same active pharmaceutical ingredient (API) as the original, but it may differ in some characteristics such as the manufacturing process, formulation, excipients, colour, taste, and packaging. Generic products become available after the patent protections afforded to the drug's original developer expire. Definition of Generic Bioequivalence According to US FDA regulations, a generic drug product is one that is comparable to an innovator drug product in dosage form, strength, and route of administration, quality, performance characteristics and intended use [1].

Applications to the FDA for approval of generic drugs are considered “abbreviated” because they generally do not include preclinical (animal) and clinical (human) data in order to establish safety and efficacy. Generic drug manufacturers must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug) .To be considered bioequivalent, the generic version must deliver the same amount of active ingredients into the bloodstream in the same amount of time as the innovator drug [2].

Branded drugs

A drug that is patent-protected and sold by a pharmaceutical business under a particular brand name or trademark. Brand-name medications may be bought over the counter or with a prescription. Any pharmaceutical product that is covered by the Plan's pharmacy benefit and is prescribed, including over-the-counter medications supplied in accordance with a prescription, medicine, agent, substance, device, supply, or

other therapeutic product that is not a generic drug, is referred to as a "Brand Drug" or "Brand." [3].

The corporation must first file a New Drug Application and receive permission from the Food and Drug Administration (FDA) before they can promote and sell their product. The corporation provides information in this paperwork to prove the clinical safety and effectiveness of a medication. A medication considered innovative is one that was developed with its particular active component and was approved for use initially. The majority of medication patents are valid for 20 years. Until the patent expires, no other company is allowed to sell the identical medication throughout the patent term[4].

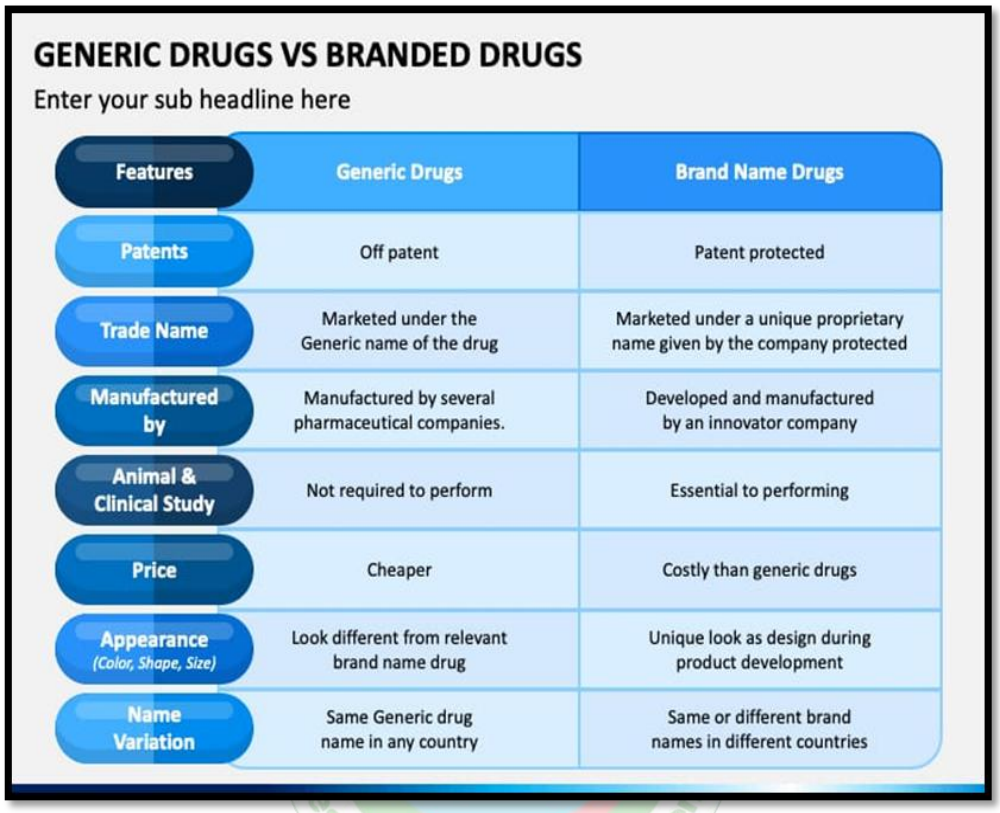

Figure 1: Comparison between Generic and Branded drug

Diabetes

Diabetes is a chronic illness characterized by elevated levels of blood glucose, accompanied by disturbed metabolism of fats and proteins. Because the cells are unable to metabolize the glucose owing to either insufficient insulin secretion by the pancreas or inefficient cell use of the generated insulin, blood glucose levels rise [5]

Three main forms of diabetes exist:

Insulin dependent diabetes mellitus (IDDM): Diabetes, in which the pancreas fails to produce insulin.

Non-Insulin dependent diabetes mellitus (NIDDM): Diabetes, in which body cells become resistant to the action of insulin produced.

1. Type 1 diabetes

Insulin insufficiency and subsequent hyperglycemia are the gradual outcomes of type 1 diabetes mellitus (T1DM), an autoimmune illness that disrupts the pancreatic β-cell responsible for generating insulin. The goal of treatment is to replace the natural β-cell function with exogenous insulin and continuously monitor blood glucose levels in an attempt to restore and sustain euglycemia [6]

2. Type 2 diabetes

Due to insulin resistance, decreased insulin production, and ultimately pancreatic beta-cell failure, type 2 diabetes is characterized by insulin insensitivity. The liver, muscle cells, and fat cells receive less glucose as a result of this. When blood sugar levels are high, there is a rise in fat breakdown. Hyperglycemia occurs from low insulin levels combined with increased insulin resistance [7].

3. Gestational diabetes

More insulin is required as pregnancy progresses on because growing tissue resistance to insulin occurs. The vast majority of pregnancies have easily met demand, so the equilibrium between Insulin supply and resistance are sustained. But when resistance takes over, women experience hyperglycemia. Insulin resistance typically increases during the latter half of pregnancy and then, most of the time, rapidly disappears after delivery. When tissue needs for proper blood glucose management are not met by the available insulin, hyperglycemia ensues[8].

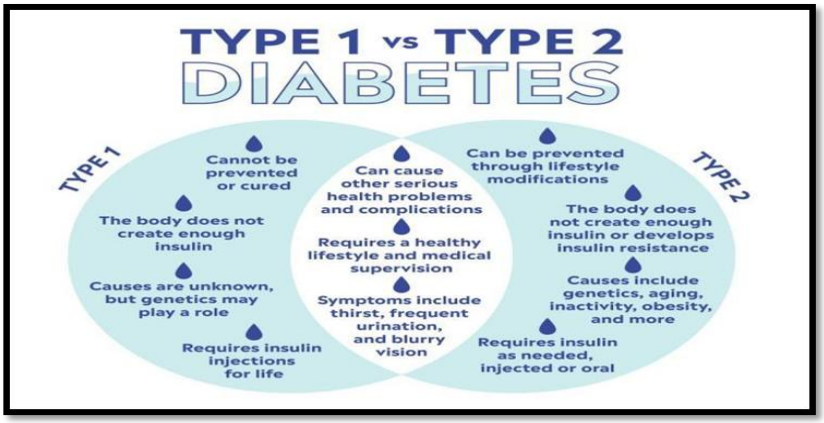

Figure 2: Comparison between Type 1 and Type 2 Diabetes

Global and economic impact of diabetes:

According to global statistics around 380 million people are suffering from diabetes of which 80-90% of the cases are of type 2 diabetes. India currently records 68 million cases of diabetes approx. and the number is expected to increase up to 80 million till year 2025. According to WHO predictions, by 2030 diabetes will rank as the seventh most common cause of death worldwide. In 2004, it is estimated that 3.4 million individuals lost their lives as a result of high blood sugar [9].

Discussion

How diabetes economically affect India

Several studies have shown that people with diabetes generally spend a larger proportion of their income on care, spend more money overall, and the cost of complications contributed significantly to overall cost diabetes study Medical costs for people with diabetes are typically 2.3 times higher than they would be in the absence of the disease. Individuals with a diagnosis of diabetes typically spend USD 16,750 on medical expenses annually, of which USD 9,600 is directly related to the disease. The estimated median annual direct and indirect costs of providing care for diabetes in India were ₹ 25,391 and ₹ 4,970, respectively [10].

The estimated lifetime cost of all medications used to treat diabetes is ₹ 19,45, 135. The mean monthly expenditure per patient (ppm) was ₹ 1,265, of which ₹ 993 was allocated for medical expenses and ₹ 271 for nonmedical expenses. The annual total cost of care (COI) for diabetic patients was ₹ 22,456 [11].

Per capita income of India

An average per capita income of a Indian families in rural parts of India was found to be 1, 67,833 INR and expenses were estimated to be around 1, 30,557. The average income of urban Indian family was found to be 2, 67,656 INR, where the expenses were found to be 1, 88,738. According to statistics the average income of families across was estimated to be 2, 02,076 INR while the expenses were found to be 1,50,515INR . Between 2004 and 2005 Farm-oriented income was at 45.1%, with 12.8% coming from manual wage labor, and non-farm income was at 46.1%, with 8.8% coming from other residual sources [12].

Farm-oriented income is at 45.1%, with 12.8% coming from causal wage labor. From the 34.8% recorded in 1993–1994 to the current 11.7% , the non-farm income share has increased, with 6.4 percentage points coming from other sources. The income from agriculture has increased from 7.9 percent to 12 percent, but the share from cultivation has decreased from 55 percent to 33 percent. Although the non-farm sector is a significant source of income, it's shocking to note that the majority of the improvement has come from a significant increase of 6.5% in casual non-agricultural labor, followed by an approximately 4% increase in salary and professional services[13].

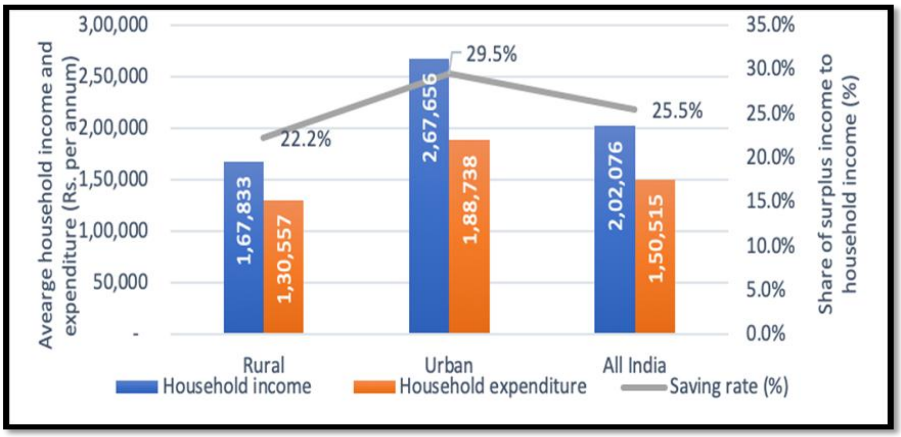

Figure 3: Income spent of antidiabetic drugs in India

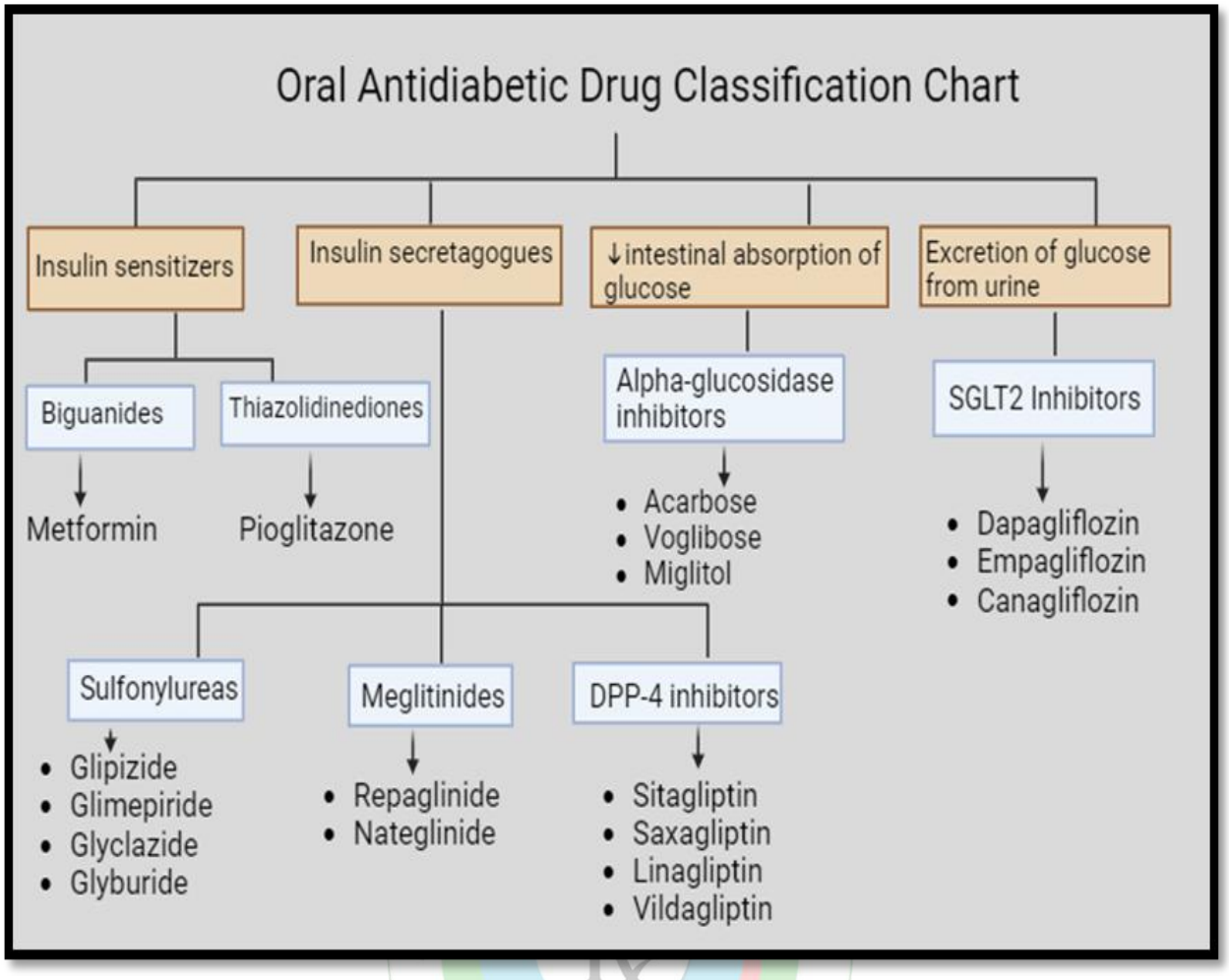

Figure 4: Antidiabetic Drug

Types of pharmacological agents used in treatment of diabetes

1. Biguanides

Metformin a drug most prominent in the category of biguanide is the most often prescribed medication for patients who are overweight or obese, suppress the production of glucose by the liver, raise insulin sensitivity, improve glucose uptake by phosphorylating GLUT-enhancer factor, increase fatty acid oxidation, and reduce the absorption of glucose from the gastrointestinal tract [14].

2. Sulphonylureas

The Sulfonylurea's are usually well tolerated, but there is a chance of hypoglycemia because they increase the body's natural production of insulin. For elderly patients with diabetes mellitus, short-acting Glipizide should be used instead of long-acting sulfonylureas like glyburide. [15].

3. Meglitinides

Meglitinide have similar mechanism of action to sulfonylurea, but with a different binding site, repaglinide and nateglinide are non-sulfonylurea secretagogues that stimulate the release of insulin from the pancreatic beta cells by acting on the ATP-dependent K-channel. [16].

4. Thiazolidinediones

Thiazolidinedione are Diazoline derivatives Insulin sensitizer thiazolidinedione selectively binds to the transcription factor peroxisomes proliferators-activated gamma. Pioglitazone is the main medication in this class, as the Food and Drug Administration (FDA) recently advised against the restricted use of rosiglitazone due to an increase in cardiovascular events associated with the medication. Because pioglitazone is well tolerated by older adults and can be used in cases of renal impairment, it is not linked to hypoglycemia [17].

5. Alpha glucosidase inhibitors

Acarbose, voglibose, and miglitol are probably safe and effective treatments for type 2 diabetes. Avoid using these medications in patients who have severe renal impairment as they are most useful for treating postprandial hyperglycemia[18].

6. DDP-4

Inhibitors of Dipeptidyl-Peptidase IV Dipeptidyl-peptidase (DPP) IV inhibitors increase the levels of these hormones that are active and, as a result, improve islet function and glycemic control in type 2 diabetes by inhibiting dipeptidyl peptidase-4 (DPP-4), a ubiquitous enzyme that quickly inactivates both GLP-1 and GIP. When combined with metformin, thiazolidinediones, and insulin, they are useful as add-on therapy Cost of antidiabetic in India[19].

Table 1: Average cost of branded antidiabetic drugs**:** [20].

Name of drugs	Minimum cost of drugs	Maximum cost of drugs	Average cost of drugs
Tab. Glibenclamide 5 mg	6.71	9.85	8.28
Tab. Gliclazide 30 mg	18.22	81.4	49.81
Tab. Glimepiride 1 mg	14.50	40.10	27.3
Tab. Glipizide 5 mg	4.55	7.25	5.9
Tab. Metformin 500 mg	13	67	40
Tab. Pioglitazone 15 mg	15	59.99	37.495
Tab. Repaglinide 1 mg	44	95	69.5
Tab. Voglibose 0.2 m	21	95	58
Tab. Acarbose 25 mg	54.50	83.50	69
Tab. Teneligliptin 20 mg	55	130	92.5
Tab. Vildagliptin 50 mg	69	110	89.5

Table 2: Average cost of Generic antidiabetic drugs[21].

Name of the drug	quantity	Generic price of drug (in INR)
Tab. Vildagliptin 50 mg	15 tab.	255
Glimepiride 1mg	10 tab.	40
Teneligliptin 20mg	10 tab.	115
Repaglinide 15mg	10 tab.	179.05
Pioglitazone 15mg	10 tab	33
Metformin 500mg	20 tab	33.70
Voglibose 0.2mg	10 tab	74.00

Table 3: Comparative cost analysis of branded and generic antidiabetic in India[22].

Name of drug	Cost of branded antidiabetic drug	Cost of generic antidiabetic drug	Cost variation
Metformin 500mg	13	2.22	83%
Voglibose 0.2mg	21	4.12	81%
Pioglitzone 15 mg	15	3.33	78%
Glimepiride 1mg	14.50	4.00	73%
Teneligliptin 20mg	55	11.5	79%
Repaglinide 15mg	44	11.9	73%
Vidagliptine 50mg	69	17	75%
Acarbose 25mg	54.50	9.79	82%
Glicazide 30mg	18.22	2.67	86%

Evaluation of generic tablets

1. Hardness

The Monsanto hardness tester was used to assess the tablet's hardness. The observed outcomes demonstrated that the crushing strength and hardness of each of the chosen brands of Metformin are both suitable. If the tablet's crushing strength is between 4 and 10 kg/cm3, it passes the hardness test. [25].

2. Friability

Every chosen brand was weighed before being put in the Roche friability device. The tablets' percentage reliability satisfies IP specifications. It stipulates that the study's friability cannot lose even 1% of its starting weight. [26].

3. Disintegration

Improved bioavailability leads to improved absorption and, ultimately, improved therapeutic efficacy; disintegration is necessary for this. According to the disintegration test findings, both generic and branded Metformin tablets dissolve in less than 10 minutes, which is shorter than the typical disintegration period. This indicates that all of these brands of Metformin tablets surpass the pharmacopoeia's quality control requirements.

Survey:

Survey is carried out on the pharmacist working in pharmacy selling generic medicine only and the diabetic patients visiting the pharmacy. A questioner was prepared on the basis of which the survey was carried out.

Questionnaire for Pharmacist

1. What percentage of diabetic medications you dispense are generic drugs?

Ans. Around 25% of the generic drugs dispensed from the pharmacy belongs to the category of Oral-hypoglycemic.

2. Have you noticed any difference in patient adherence when it comes to generic v/s brand name diabetes drugs?

Ans: Yes, consumers nowadays prefer generic oral hypoglycemic over branded name drugs due to their cost effectiveness.

3. Do you believe that generic diabetic drugs are as effective and safe as their brand name counterparts?

Ans: generic medicines are as effective and safe as branded medicines giving the same therapeutic efficacy and activity.

4. Are there specific generic diabetes drugs or classes of medications that you find more commonly prescribed or requested by healthcare providers?

Ans: Oral hypoglycemic having class Biguanides containing drug Metformin are more prescribed by healthcare providers over any other category drugs. [27,28].

Question for patients visiting the generic pharmacy:

1. Do you believe that generic medicines give same

therapeutic effects as that of branded medicines?

Ans. Yes, they give the same therapeutic activity as that of branded medicine.

2. Do generic medicine have any positive impact on your monthly budget?

Ans: yes, generic medicine saves 60-70% of cost effectiveness than branded medicine.

3. Do you see any adverse effect after using generic medicines?

Ans: no, we didn't observe any adverse effect after continuous administration of generic drugs. [29, 30].

Figure 8:- Generic and branded drugs store visited for survey

Conclusion from study

After the collection of data from customer and pharmacist. Generic drugs are more cost-effective and highly reliable drugs. They are easily available and have a high consumption rate due to their minimum cost price. As per the consumer opinion, the safety and efficacy of these drugs are similar to that of branded drugs. Due to the consumption of generic medicine, a small portion of income is spent on the consumption of diabetic medicine, which can be spent on other necessary needs.

On average there is a difference of 75-80% in the cost of generic and branded medicine. In conclusion chemist and patient can give preference to generic medicine which will save the cost of medicine as well as gives the same effect as like branded medicines.

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