

ACCESS TO ESSENTIAL MEDICINES FOR HYPERTENSION, DIABETES AND PSYCHOSIS THROUGH DIFFERENTIAL USAGE OF GENERIC AND BRANDED MEDICINES IN JOS AND ENVIRONS, NIGERIA

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Abstract

Background: Generic medicines have become the mainstay in low and middle-income countries like Nigeria. The cost of branded pharmaceutical products has necessitated the policy for their usage in public health facilities and all health facilities where the National Health Insurance Scheme policy (NHIS) is applied.

Objective: The study accessed the availability and affordability of generic medicines used to manage hypertension, diabetes and psychosis in Jos and its environs in Nigeria.

Methods: A descriptive, cross-sectional study was done using the WHO/HAI methodology 2008. This was used through an adopted questionnaire to measure the prices of selected Branded and generic incarnates of essential medicines in public and private pharmacies within a particular distance of one hour and three hours drive from the reference hospital (Jos University Teaching Hospital (JUTH) Jos) in a day. The mean prices of the lowest generic and branded were also noted in the principal health facilities and at least five retailed pharmacies nearest them. Data Analysis was done using the IBM SPSS version 20 software to calculate prices of generic and branded antihypertensive and antidiabetic baskets of essential medicines.

Results: It was observed that 68% of branded products were prescribed more in private health facilities, lisinopril, amlodipine and frusemide among the antihypertensive while branded metformin (82%), glimepiride (27%) and glibenclamide (9%) were the most prescribed antidiabetics. The following antihypertensives were found available in private health facilities according to WHO/HAI 2008 (moduretic, methyldopa, vasoprin, propranolol and nifedipine), while (moduretic, methyldopa, vasoprin, amlodipine, frusemide, lisinopril and captopril) were available in public health facilities. Branded insulin, metformin 500mg, pioglitazone 15mg, repaglinide 1mg and sitagliptin 25mg those prices were higher than generic and international reference prices. For the antihypertensives, most generics except Olmesartan 5mg, Hydralazine 20mg, ramipril 5mg, timolol 0.25%, torsemide 5mg and Verapamil 100mg were higher than the international reference prices. For the antipsychotics, most of the international reference price products were higher than their generics and branded; however, carbamazepine 200mg was exceptionally higher (branded).

Conclusion: Access to essential medicines in developing economy like Nigeria are mostly affected by branded products with trade-related intellectual property rights. Generic incarnates of such medicines in the above study showed that branded products were not cost-effective compared to their generic versions in treating hypertension, diabetics and psychosis. Branded products were mostly used in private health facilities, explaining the incremental cost compared to the public health facilities.

Keywords: Access to medicines, generic, branded, hypertension, diabetes and antipsychotics

Introduction

A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use ^[1]. On the expiration of the originator product's patent term protection, other manufacturing companies may file submissions to regulatory authorities for approval to market generic versions of the originator medicine. Generic drugs may be marketed under the non-propriety (rINN) name or as a branded generic.

The World Trade Organization, through the DOHA Declaration 2001, had affirmed the right to health towers high and above Trade-Related Intellectual Property Rights (TRIPS). This allows for the incarnation of branded pharmaceutical products into generic versions with equal potency and generation of action at lower prices.

Essential medicines satisfy the general healthcare needs of the populace. Essential medicines are crucial towards achieving the Universal Health Coverage and Sustainable Development Goal. Sustainable Development Goal 3.8 addresses the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of universal health coverage (UHC), and Sustainable Development Goal 3. b emphasizes the need to develop medicines to address persistent treatment gaps ^[2].

To make essential medicines available to the poorest of the poor, as was stated for Africa, the Bamako initiative came up in 1987 in Mali to improve health care quality among the poorest of the poor ^[3]. Nigeria has the largest pharmaceutical manufacturing sector in the West African sub-region, estimated to be about 65% of the total West African value. The pharmaceutical market in Nigeria was estimated to be USD 1.9 billion in 2013, with more than 30% derived from generic medicine, 24% from branded products and 40% from over-the-counter products (OTC) ^[4].

Generic medicines have the same therapeutic actions as branded medicines. They constitute 80% of prescription drugs sold worldwide and in Nigeria. Generic and brand-name medicines act similarly and have the same effect on individuals. They have the same active ingredients, side effects, route of administration, risk and safety. They are substantially cheaper than the branded ones. Branded drugs cost more due to the cost of research and development (R & D), Clinical trials, registration and approvals in operating countries, and marketing costs, all factored into the brand cost. Generic drugs are used in public health facilities and Essential Medicines List (EML).

Frost & Sullivan gave a projection that a Compound Annual Growth Rate (CAGR) of 13.2% on revenues of USD 2.61 billion in 2016; it further stated that the local pharmaceutical market growth will be driven mainly by increasing the availability of low-cost generic drugs and an improving regulatory environment⁴. Traditional diseases are common in poor, middle-income countries. Malaria, bacterial infection, diarrhoea, and perinatal conditions will continuously increase. Also, prominent non-communicable lifestyle diseases like hypertension, diabetes, hyper-cholesterolemia and cancer are increasing. All these are expected to lead to the industry's growth due to increased demand for chronic disease medicines⁵. Most physicians in private hospitals in Malaysia have a negative perception of generic drugs with consequent limited use in private health facilities, thereby relying more on unbranded medicines for their patients' use ^[6]. Prescription of drugs for chronic diseases in each health facility is done by physicians under some Standard Treatment Guidelines (STG), Essential Medicine List (EML) and Drug Formulary Committee (DFC).

Medicines are generally more affordable in high-income countries than in low-income countries when adjusted for national or individual income levels ^[7]. In many low-and middle-income countries, treatments for acute and chronic diseases are paid mainly out of pocket, making them unaffordable, especially in the private healthcare sector, and they may be unavailable in the public sector in Nigeria ^[7]. The price and affordability of essential medicines are governed by improving market competition, price control and firm generics policy ^[1].

The drug formulary in each health facility (HF) is developed and overseen by various internal committees, namely the Drug Management Committee (DMC), Drug Advisory Committee (DAC), and drug formulary committee (DFC). The role of the DMC, among others, is to see the overall drug management of the HF, whereas that of the DAC is to review new drugs and new indications for the HF drug formulary. The DFC also reviews the existing drug lists to remove obsolete drugs and evaluate the indications for special drugs when necessary. All members of these three committees may include the chairman of the cluster service and the director of pharmaceutical services/HOD pharmacy of the

HF, the director of Nursing services, and two academics in healthcare-related disciplines from local universities. They are responsible for the centralized decision process for the drug formulary. In addition, patients are advised about the nature of the drugs they are taking, which could be generic or branded products, through accurate labelling. Patients should be reminded to record any potential adverse drug reactions (ADRs)/side effects or alert their physician if they feel unwell if any medications are switched.

The supply and demand factors determine brand and generic drug substitution, *ce-teris paribus*. The supply side factors include free pricing of medicines (e.g. Germany, Netherlands, United Kingdom) than in countries with pricing regulations (e.g. Australia, Belgium, Italy, Portugal, Spain). This is because countries that adhere to free market pricing generally have higher medicine prices, facilitating market entry of generic medicines and a higher price difference between originator and generic medicines. The demand-side policy includes generic-only prescribing, substitution, procurement, and reimbursement. Also, generic interventions are anchored on ensuring the quality of essential medicines by enforcing good manufacturing practice (GMP) 100% adherence ^[2]. This study assessed the availability and affordability of essential medicines used in managing hypertension, diabetes and psychosis from a basket of medicines.

Methods

The difference in cost is calculated by using the formula.

$$\frac{100 \times (\text{MPR} - \text{PTR})}{\text{PTR}}$$

PTR

MPR – Maximum Price Ratio

PTR – Price to Retailers

$$\text{PTP} = \text{MPR} - \text{PTP}$$

The data were obtained from a survey using the World Health Organization/ Health Action International method^[8]. From public hospitals, private hospitals, private but faith-based hospitals, and retailed pharmacy outlets in Nasarawa state (Lafia, Akwanga and Keffi) and Plateau State (Mangu, Barkin-Ladi,) Jos and environs, retail or selling prices in all health facilities were compared. The prices in the aforementioned retailed health facilities were compared with those of the international reference prices. The median price was used to facilitate regional and national comparisons; the reference prices were obtained from the Management Sciences for Health (MSH) International Drug Price Indicator Guide ^[9]. The medicines included in the secondary analysis were represented as originator and generic equivalent medicines. A complete list of the medicines included in the secondary analysis can be found in Table 2. Lovastatin indicated for reducing serum lipid concentrations, has not been included since very few data were available. Retail prices of the basket of essential medicines were collected from forty (40) retail pharmacy outlets, including public and private hospitals. All could be accessed within a three (3) hour drive from Jos the central area. The retail pharmacy sample was chosen based on their proximity to the public health facilities surveys; at least five (5) pharmacies per survey area were considered. Prices were compared with the international reference prices.

Results:



Figure 1: Access framework. Source: WHO, 2000

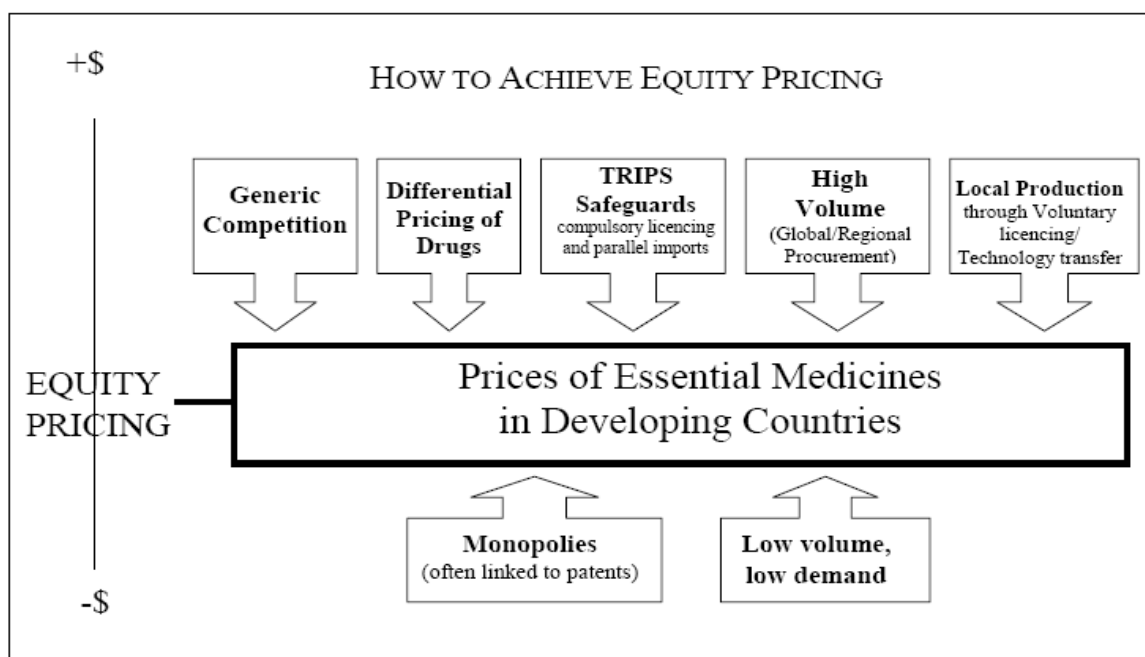


Figure 2: Affordable prices. Source: (WHO, 2016)

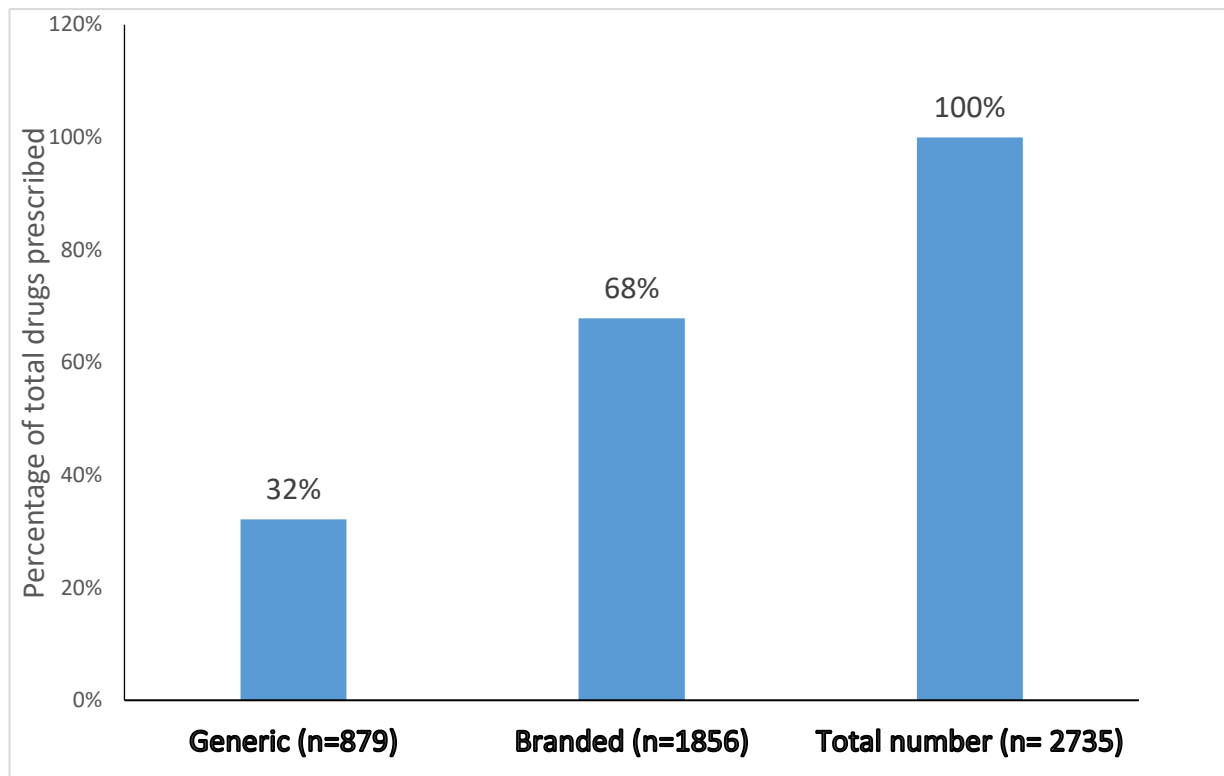


Figure 3: Pattern of generic prescribing.
The total n value in Figure 3 above should be a capital letter "N."

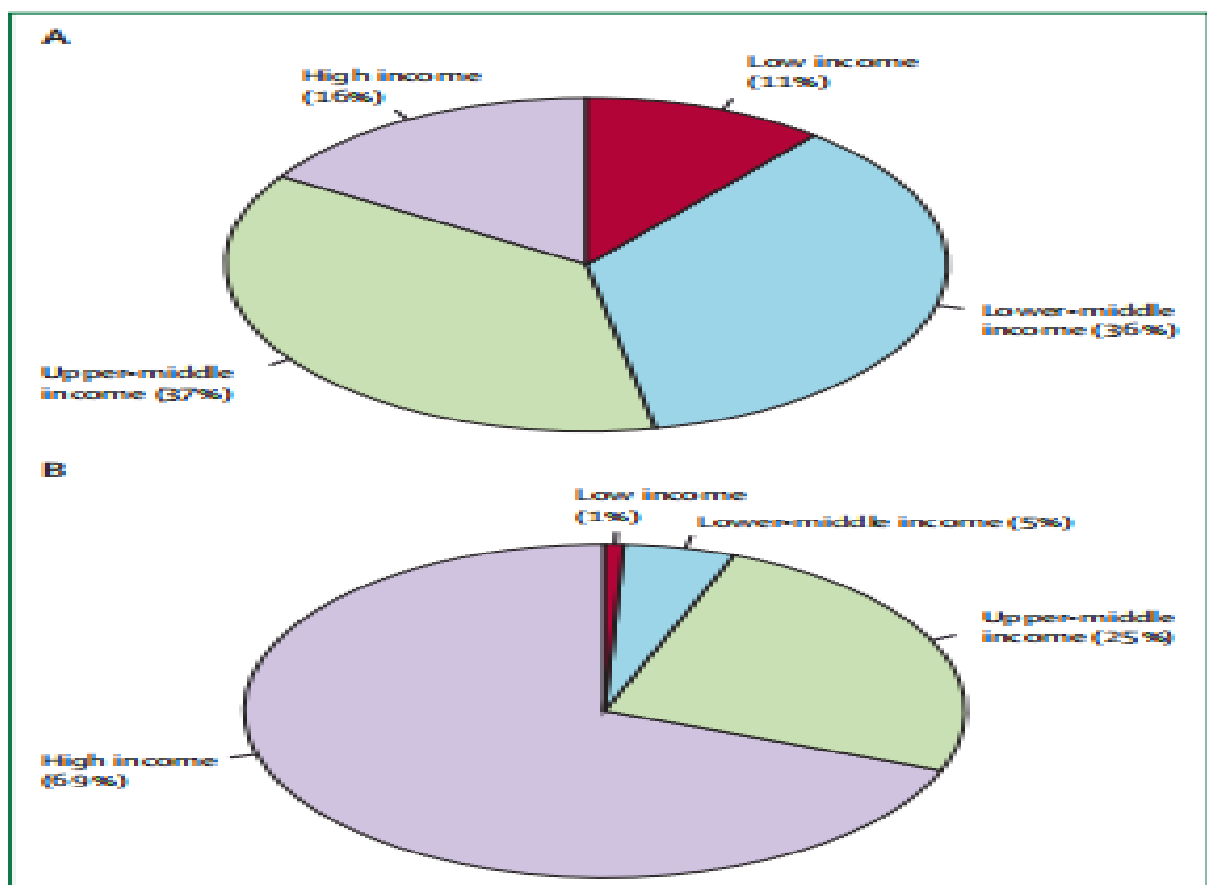


Figure 4: Distribution of world population (A) and total pharmaceutical expenditure (B) in different economic categories in 2010

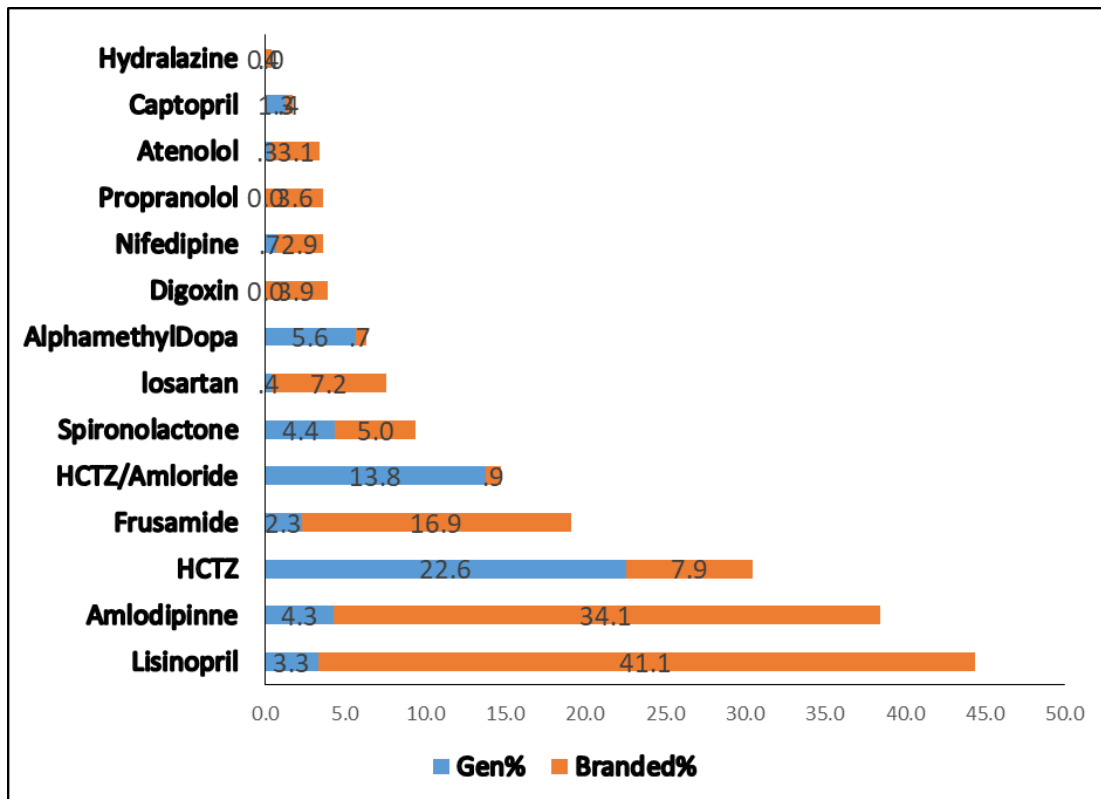


Figure 5: Antihypertensive consumption pattern of medicines according to brand and generics

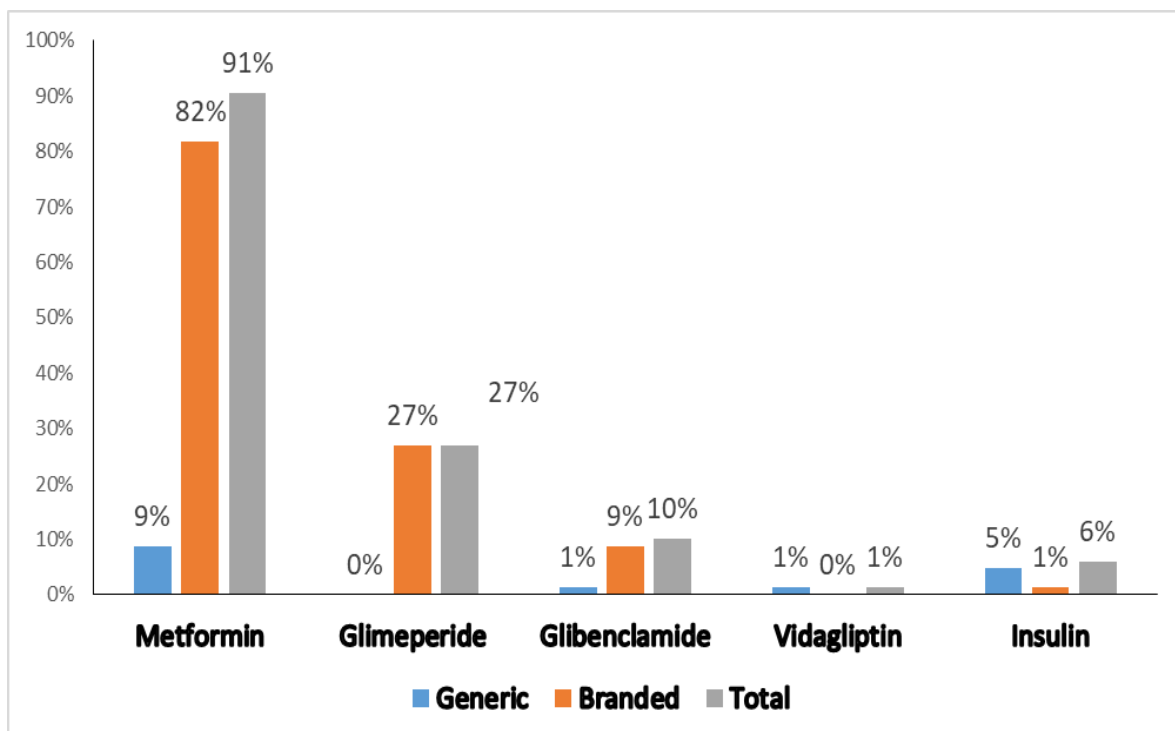


Figure 6: Antidiabetic consumption pattern amongst generic vs. branded

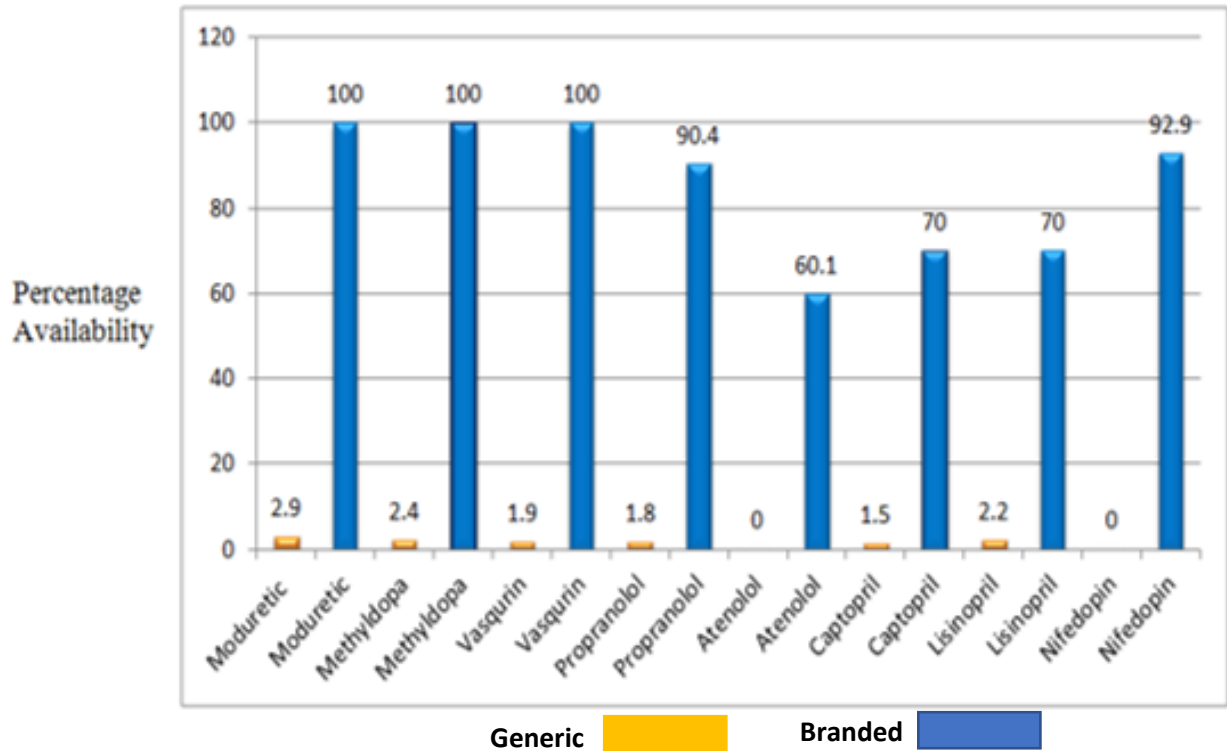


Figure 7: Percentage availability of generic versus branded medicines in the Private Health Sector (Antihypertensive)

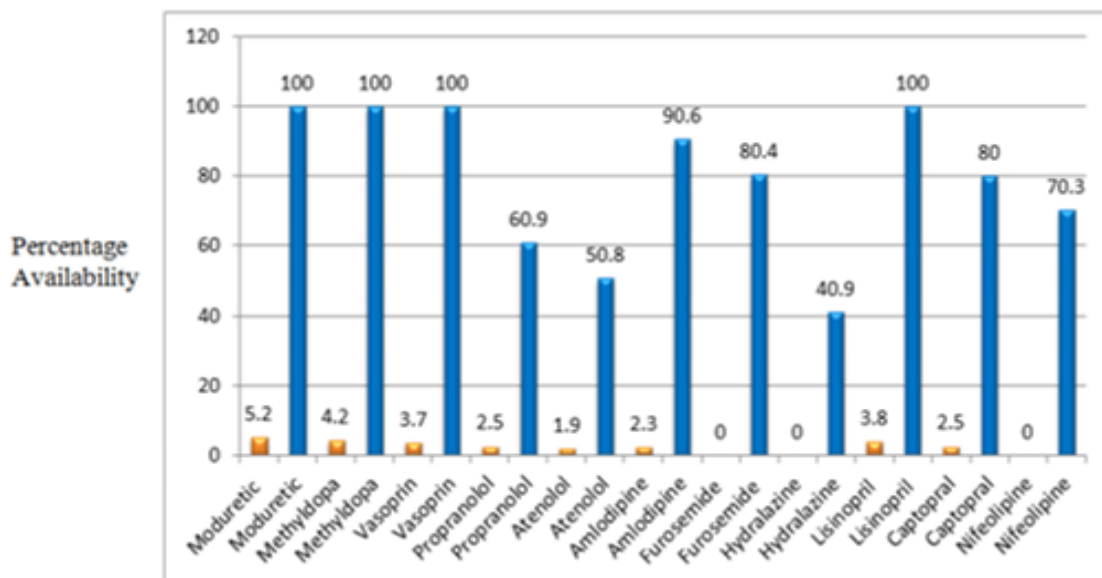


Figure 8: Percentage availability of generic versus branded medicines in the Public Health Sector (Antihypertensive)

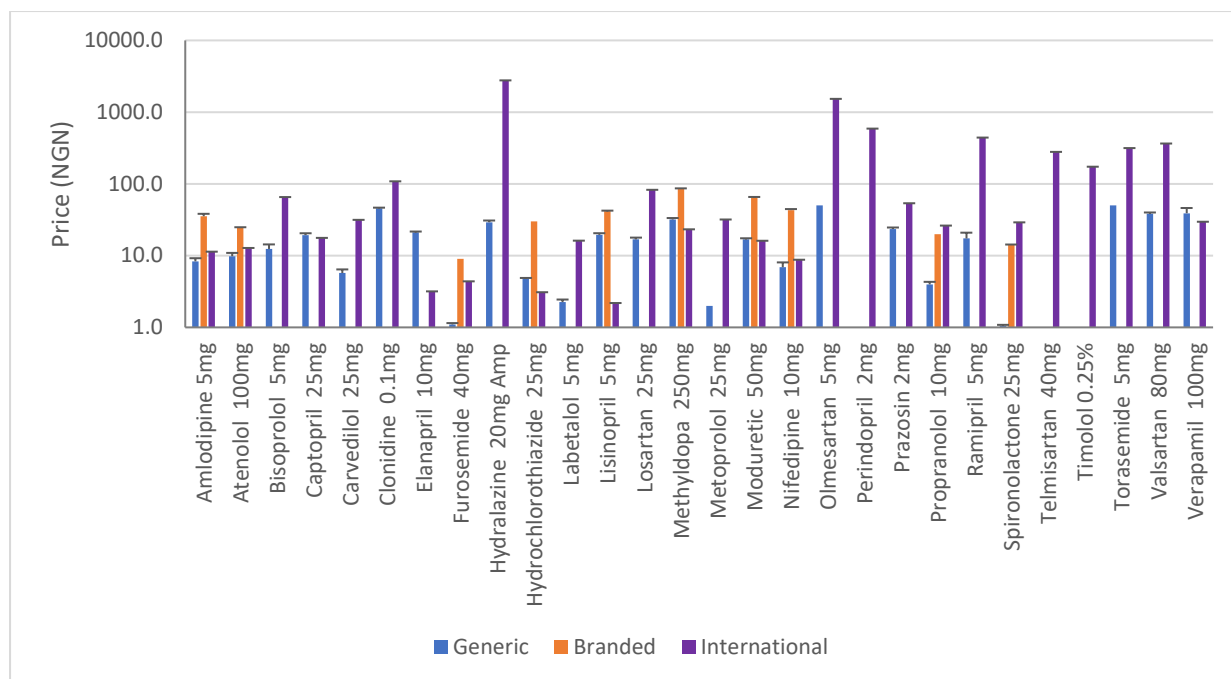


Figure 9: Comparison of the prices of antihypertensive medicines with the international reference prices

Table 1

Unit prices of the medicines available on the pharmacy premises

Medicine Name	Generic Unit Price*		Branded Unit Price*		Reference Price*
	n	Mean ± SD	N	Mean ± SD	
Antidiabetics					
Acarbose 25mg	1	318.7	1	318.7	318.7
Dapagliflozin 5mg	1	6,911.10	1	6,911.10	6,911.10
Glibenclamide 5mg	39	7.7±7.7	1	4.1	4.1
Gliclazide 30mg	1	23.4	1	23.4	23.36
Glimepiride 2mg	37	34.7±13.4	1	6.3	6.25
Glipizide 5mg	5	24.0±42.4	2	75.0±35.3	99.91
Glyburide 5mg	37	14.8±28.7	1	183.2	183.24
Insulin (soluble 40IU)	37	3,463.9±1,102.8	25	6,066.6±1,517.7	163.88
Linagliptin 5mg	1	592.4	1	592.4	592.38
Metformin 500mg	39	15.5±24.9	22	82.1±40.2	150.5
Nateglinide 60mg	24	39.2±123.4	1	609.8	609.76
Pioglitazone 15mg	28	50.3±28.0	16	104.7±21.0	150.5
Repaglinide 0.5mg	1	900.8	1	900.8	900.81
Repaglinide 1mg	5	240.1±497.7	1	1,130.30	1,130.26
Sitagliptin 25mg	2	3,829.3±5,408.3	1	7,653.50	7,653.55
Antihypertensives					
Amlodipine 5mg	37	8.3±5.4	26	35.4±14.8	11.36
Atenolol 100mg	38	9.8±6.8	31	24.4±2.9	12.79
Bisoprolol 5mg	5	12.4±4.3	0		65.55
Captopril 25mg	39	19.3±7.3	0		17.68
Carvedilol 25mg	7	5.7±1.9	0		31.55
Clonidine 0.1mg	6	45.8±2.0	0		108.6
Elanapril 10mg	31	21.1±3.2	0		3.18
Furosemide 40mg	40	1.1±0.3	35	9.0±0.0	4.38

Hydralazine 20mg Amp	39	29.2±10.5	0		2,772.81
Hydrochlorothiazide 25mg	40	4.8±0.7	1	30	3.09
Labetalol 5mg	32	2.3±1.1	0		16.17
Lisinopril 5mg	40	19.6±6.1	29	41.6±4.5	2.19
Losartan 25mg	39	16.8±6.4	0		82.73
Methyldopa 250mg	39	31.9±9.7	32	85.0±9.5	23.29
Metoprolol 25mg	2	2.0±0.0	0		31.91
Moduretic 50mg	39	16.8±3.9	36	64.0±10.5	16.13
Nifedipine 10mg	39	6.9±7.2	21	43.1±6.6	8.77
Olmesartan 5mg	2	50.0±0.0	0		1,532.29
Perindopril 2mg	0		0		589.62
Prazosin 2mg	37	23.5±7.4	37	1.0±0.0	53.75
Propranolol 10mg	39	4.0±2.1	34	20.0±0.0	26.23
Ramipril 5mg	6	17.3±8.7	0		442.31
Spironolactone 25mg	40	1.1±0.2	7	14.1±0.4	29.11
Telmisartan 40mg	0		0		279.5
Timolol 0.25%	0		0		173.65
Torasemide 5mg	1	50	0		315.54
Valsartan 80mg	8	38.3±4.8	0		365.5
Verapamil 100mg	38	39.0±44.1	0		29.68

*prices estimated in Nigerian Naira (NGN) (1 USD = 395 NGN as of 21/01/2021);

Reference Price = price based on the International Medical Products Price Guide and the Nigerian National Health Insurance Scheme (NHIS) price list, adjusted for exchange rate and consumer price index (CPI); n = number of pharmacy premises having the medicine in stock, whose prices were used out of the 40 pharmacy premises evaluated; SD = standard deviation

Table 2:

Branded and Generic prices of Antipsychotics compared to International Reference Prices

	Medicine NGN	MP Generic 2 (USD)	Brand 1 (USD)	International Reference Price (USD)
Carbamazepine	29.00	1.2543	7.4080	0.0223
Allopurinol	30.00	5.0360	0.0000	0.0260
Benzhexol	31.00	0.1452	0.0000	0.0562
Risperidone	33.00	6.2620	0.0000	0.0268
Olanzapine	34.00	0.7653	0.0000	0.1200
Valporate	35.00	0.0000	0.0000	0.0842
Chlorpromazine	38.00	3.8032	0.0000	0.0286
Fluphenazine	42.00	0.0453	0.0000	1.7249
Chlorzapine	43.00	2.5982	0.0000	0.1055
Aripiprazole	44.00	0.0000	0.0000	0.1223

Discussion

Access to essential medicines, which is a prerequisite towards achieving universal health coverage and the sustainable development goals for 2030, as stated by WHO in Figure 1, is covered by four main areas, namely: Rational use, affordable prices, Sustainable Financing, reliable health and supply systems, Affordable/equitable pricing can be achieved through the use of generic competition as seen in figure 2^[2]. Most prescriptions obtained in Figure 3 were branded 68% (1856), while generics accounted for 32% (879). The world population is majorly covered by the low-and-middle-income

class, with only 16% of the high-income class. The high-income countries contribute to 69% of the market, while the LMC are responsible for only 31%.

Most of the antihypertensive drugs consumption patterns were branded products, namely lisinopril, amlodipine, frusemide, propranolol, atenolol and nifedipine which constituted more than 90% compared to the few generic prescriptions of Hydrochlorothiazide (HCTZ), Hydrochlorothiazide (HCTZ)/Amiloride, Alpha Methyl dopa and Captopril as shown in figure 5. This also agrees with the findings by ^[10]. These findings of branded drug prescription are similar to those found in Hong Kong, where public health facilities used branded medicines as an alias for a drug because these are easier to remember¹¹. However, this differed from that obtained in Japan with higher generic use due to pharmacists and doctors giving financial incentives to use generic drugs since 2006 ^[12].

The antidiabetic consumption pattern showed a mostly branded product profile, with metformin usage of 68.5% being the highest. Other antidiabetics, namely insulin and Glimeperide, had a higher branded drug prescription. However, 15.7% of all the glimepirides were generics, as shown in Figure 6. This also corroborates with the findings of 10. A sharp contrast was observed by ^[13], where 90% of metformin was generic.

The availability of branded antihypertensives in private health facilities became more prominent, as shown in Figure 7 than their generic counterparts. Five of eight antihypertensives were equal to or greater than 80% available based on ⁸ criteria, as shown in Figure 7. Our findings agreed with that of ^[14]. A similar availability pattern of antihypertensive in the public health sector, with 8 out of 12 drugs available than their generic counterparts, is shown in Figure 8. This also corroborates the findings by ^[14].

Compared to the international reference price, it was observed that branded products had higher prices compared to their generic counterparts. However, some exceptions showed higher international prices than branded and generic prices, as shown in Figure 9. These findings differed from that of ^[14], where the use of generic drugs was far more cost-effective and thought it may save money. Table 1 showed that among the antidiabetics, the standard deviation and prices of insulin, repaglinide and sitagliptin (3,463.9 – 6,066.6 and 3,829.3 – 7,653.50), respectively, were higher compared to the price to the patient (PTP) which is equal to MPR-PTR. Antihypertensives like Hydralazine, Olmesartan, perindopril, ramipril, timolol, torsemide, valsartan and verapamil were higher than a patient's price.

The antipsychotic consumption pattern consisted of a mixture of typical and atypical combinations used concurrently. It was also observed that most generics had higher prices than the branded and international reference prices, which differed from those obtained from ^[15]. However, the branded carbamazepine was priced higher than the generic and international reference price. The generic versions of antipsychotics were costly, unlike the branded antihypertensive and antidiabetics, whose prices were higher than their generics and international reference prices. Generics do not always lead to the anticipated monetary savings and raise compliance issues.

Conclusion

Access to essential medicines for chronic diseases like hypertension, diabetes and psychosis is affected by the availability and prices of the products used in their management. Generic and branded versions of these products were used concurrently. However, it was observed that more branded antihypertensive and antidiabetic products were more available and widely used in managing the respective diseases. Generic antipsychotic medicine usage agreed with the generic usage policy in public health facilities observed. However, this was the reverse in the consumption of antihypertensive and antidiabetes, which is against the policy of generic prescription. A wide price margin between branded and generic medicines suggested that prescribing physicians and pharmaceutical care/ dispensing pharmacists should adhere to prescribing and dispensing of generic medicines. The generic prescription policy encourages the availability and affordability of generic medicines in public health facilities due to the wide cost variations and the out-of-pocket expenses incurred in purchasing essential medicines for chronic diseases. Policies targeted at physicians, pharmacists, patients and pharmaceutical companies for generic drug usage will positively increase generic drug usage, availability, price and production.

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Recommendations

For the availability and affordability of essential medicines in resource-limited countries, policies on generic medicines, which have only been restricted to public health facilities and facilities operating the National Health Insurance Scheme (NHIS) in Nigeria, should be revisited. Public health financing using the Abuja declaration of 15% of the National budget allocated to health is strictly implemented. The multinationals in Nigeria should be advised to stop evergreening patents on hypertension, diabetes and antipsychotic drugs. They should open a license for the generic production of life-saving medicines used in chronic diseases in low and middle-income countries. They should also transfer and license the technology for producing essential medicines for chronic diseases. It is paramount to look at people's lives, the patients who are consumers of these medicines and the multinationals who should be considered most rather than the profit as stated in TRIPS.

Compliance with ethical standards

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Disclosure of conflict of interest

The Authors declare no conflict of interest of any sort.

Statement of ethical approval

Ethical Clearance with Reg no NHREC/09/23/20106, NHREC/21/12/2012 and JUTH/DCS/ADM/127/ XXV/016 were obtained from the Plateau Specialist Hospital Jos, Nigeria, Federal Medical Center Keffi, Nigeria and Jos University Teaching Hospital, Jos, Nigeria respectively.

Statement of informed consent

It is not applicable in this section as the obtained ethical clearance has covered for it.

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