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Review Article

Barriers to Implement Generic Medicine Prescribing and Dispensing Policies in Pakistan: Current Challenges and Future Implication

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Abstract

Background: Prescriptions comprising of generic names have made place as the norm in many countries owing to established drug regulatory regimes. Nevertheless, generics have greatly reduced worldwide pharmaceutical and healthcare spending. **Objective:** The current review comprehensively explores research studies focused on generic medicine in Pakistan, utilizing a variety of research methodologies. The prime objective of this review is to assess the barriers toward the implementation of generic medicine prescribing and dispensing policies in Pakistan in order to reduce the prescription cost. **Methodology:** The articles were filtered using databases: Google Scholar and PubMed. The research questions were developed and focused exclusively on all literature available regarding generic medicine in Pakistan. Results: Google Scholar and Pub-Med were searched for the period 2000-2023. 45 studies were included as per our criteria. The selected papers were grouped into different themes. Seven (7) papers were included regarding knowledge, attitude, perception & practice of healthcare givers regarding generic medicine in Pakistan. Seven (7) studies were related to Availability, Affordability, Pricing of Generic Medicine in Pakistan while 31 studies were included regarding percentage of generic prescribing as per WHO Core indicators. Both quantitative and qualitative research studies were eligible for inclusion. the selected papers were grouped into different themes. **Conclusion:** With the help of the evidence available through screening, it has been revealed that situation of generic medicine is quite alarming in Pakistan. Bioequivalence regulations as well as proper generic policy are need of the day. Educational interventions and uncompromising compliance to the drug policies of WHO may play a part in generic medication prescribing. Implementation of pricing policies is compulsory to promote rational use of drugs and to enhance availability. Presence of qualified pharmacists and electronic health system at every level of healthcare setups is need of an hour.

Keywords: generic medicine, generic prescribing, generic dispensing, generic medicine policy, WHO core prescribing indicator, Pakistan

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INTRODUCTION

Essential medicines, being an integral component of the Sustainable Development Goals (SDGs), ensures access to safe, effective, and quality medicines, along with affordable essential medicines as well as vaccines for all to help improve the health of all[1]. However, currently approximately 2 billion people worldwide have no access to the essential medicines[2]. Ultimately, this signifies that more than one quarter of the population of world are deprived of essential medicines because either they are unavailable, unaffordable, inaccessible, unacceptable or of low quality[3]. With rising healthcare costs and an unpredictable situation of worldwide economics, governments as well as payers of many countries will need to address key issues to improve the health of their

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population within available resources especially for chronic non-communicable diseases (NCDs)[4]. Increased use of generic medicines either in place of the originators or patented medicines in the same or similar classes without compromising care has the potential to considerably reduce healthcare costs across continents[5-7]. Aggressive policies to lower the prices of generics in the Netherlands resulted in generic simvastatin and generic omeprazole being as low as 2% of pre-patent loss prices; however, there are concerns that such low prices may be unsustainable[8]. Combined policies to encourage the prescribing of multiple sourced medicines versus patented medicines in a class have also resulted in considerable savings, with the monies spent on statins and proton pump inhibitors by high-income countries up to five times less when adjusted for populations sizes in countries with limited policies to encourage the prescribing of multiple sourced medicines when available[6,9]. These combined policies also resulted in the costs of lipid-lowering medicines to the healthcare systems in Scotland decreasing by 50% between 2001 and 2015 despite a 412% increase in utilization to tackle increasing levels of coronary heart diseases[10]. Currently though in ambulatory care there are few if any situations where the majority of diseases seen by healthcare professionals (HCPs) cannot be treated with multiple sourced oral medicines. This is certainly the case for anti-infective medicines where antibiotics, if indicated, should be primarily prescribed from the 'Access' list[11,12]. The only exception in ambulatory care especially in low- and middle-income countries may be inhalers for patients with respiratory diseases such as asthma[13]. However, even here inhalers from multiple sources are increasingly available to help with affordable health care enhanced by community pharmacies helping with educating patients regarding inhaler techniques[14]. Consequently, the focus on countries globally should be on increasing the prescribing of generic (multiple sourced) medicines versus originators at low sustainable prices[15].

The World Health Organization (WHO) defines generic medicines as "the 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"[16]. An originator branded drug, on the other hand, is a molecule produced by the parent pharmaceutical company after years of research and appreciable financial investment[17]. However, there can be concerns with their prices especially if Governments and other organizations have helped to appreciably fund initial research and development[18-20]. These medicines are legally patented, which will typically be the situation for many years. After a brand drug's patent expires, multiple sourced (generic) medicines can become available. Generic medicines are identical to the originator brand-name drug and contain the same active ingredient, with multiple studies showing that outcomes are the same between originators and generics where these are identical[21-24]. Generics are typically less expensive and hence typically more affordable for patients and healthcare systems because they are copies of the originator and do not require appreciable funding for the initial research and development of the molecule25-27.

Multiple policies across the Europe have resulted in low prices for generics[6,28]. Multiple policies have resulted in appreciable price reductions and savings from increased use of generic medicines whatever the population size of the country despite earlier concerns[29,30] . In Lithuania, there was a significant reduction in reimbursed expenditure/Defined Daily Dose (DDD) for generics in each medication class versus originator prices including a 56% reduction for generic omeprazole and 87% for generic atorvastatin, which resulted in easing of prescribing restrictions and more patients being well treated without resorting to 100% co-payment[29,31]. Similarly, in the Republic of Srpska, Bosnia and Herzegovina, reimbursed expenditure/ DDD decreased by up to 82% in high volume classes including acid-related stomach disorders, hypercholesterolemia and hypertension through increasing use of lower-cost multiple sourced medicines[30].Savings from the increased use of lower cost multiple sourced medicines have also been reported in Australia, Canada, Japan, and the United States, as well as low- and middle-income countries (LMICs) including the Philippines[7,32-34]. In the United Kingdom, increasing pricing transparency in the pricing of generics, coupled with very high voluntary rates of International Non-Proprietary Name (INN) prescribing, up to 99% of all prescriptions, have resulted in low generic prices[6,10,28]. Generic drugs now account for over 90% of prescriptions in the United States, which has been essential in increasing patient access to key medications[35]. Although the need for generic medicines has been demonstrated, significant work has to be done to upgrade the quality of generic medicines in low- and middle income countries (LMICs) where there can be concerns with their quality which hinders moves to encourage INN prescribing across countries[36-41].

In Pakistan is a LMIC and currently the fifth most populous country globally with a population of over 230 million in 2023[42]. Despite price controls, the affordability of medications in Pakistan remains an issue for the majority of the population owing to frequent prescribing and dispensing of originator brands (OBs) and high-priced branded generics (BGs), as well as significant price differences between OBs, BGs, and low-priced generics (LPGs)[43-45]. However, usage of medicines with low prices, either multiple sourced or branded is essential to reduce treatment costs because 77% of the population currently manage their own healthcare expenses, i.e. 100% co-pay and have an income less than five hundred rupees (USD 3) per day[46]. Most countries currently manage the cost of medicines either directly at the government or national level through formal reimbursement or contracting processes or indirectly through pharmacoeconomic methods coupled with rebates or managed entry agreements[47]. Typically, the availability and affordability of medicines is higher in countries where prices are controlled and there is universal healthcare[48]. A key strategy across countries to improve access to medicines is to encourage greater prescribing and dispensing of multiple sourced generic medicines versus originators, BGs and patented medicines in a class without compromising care[47].

In Pakistan, although implemented in 1972, the Generic Drug Act the Act was quickly repealed due to significant resistance from the commercial domain and the medical community[49].

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This Act prohibited the prescription of medications by brand or patented name, as well as the manufacturing and sales of medicines under proprietary names. The main objective of this was to bring local manufacturers at par in competition with multinational companies to help reduce the level of price hikes of medicines. However, prices did not decline considerably and the government's focus changed from price to quality. Another cause of concern was the lack of a clear pricing formula, as the current pricing practice was dependent on the reported prices with consequent opportunities for collusion to acquire high prices. This was similar to the situation in the United Kingdom before comprehensive measures to enhance transparency in the manufacturing and pricing of generics[6,50]. Consequently, in 1976, the Director General of Health issued directives for new Drug Regulating Act, which withdrew the necessity to market pharmaceuticals by their generic names and instead enforced updated manufacturing licensing requirements[51,52]. In recent years DRAP also launched its Drug Pricing Policy 2018 for the pricing of generics[53]. Currently in Pakistan, approximately, all locally produced generic drugs are labelled with proprietary trade names often referred to as "branded generics"[54]

Despite the importance of generics, generic prescribing has several limitations in Pakistan where generic drugs can be registered without bioequivalence studies[56,57]. This could result in a high number of branded generic drugs being registered in the country. Furthermore, it might lead to competition among pharmaceutical companies, as well as unethical practices in the absence of oversight of marketing and sales promotion activities[58]. This needs to be addressed going forward to enhance the availability of low cost and high quality generics similar to high income countries including the Netherlands and the UK[8].

Consequently, as a first step, we explored the current situation of generic medicines in Pakistan. This includes HCPs 's view regarding generic medicines as well as their prescribing practices, building on our recent review regarding the prescribing of antibiotics in primary care[59]. In addition, encompassing the accessibility, affordability and availability of generics in Pakistan. The findings can be used to suggest future policies in Pakistan as the country seeks to reduce morbidity and mortality particularly associated with chronic non-communicable diseases. These build on the suggestions in a recent editorial[60].

MATERIALS and METHOD

To map out the published literature regarding generic medicine in Pakistan, different aspects of generic medicines in Pakistan were assessed.

Recognizing and generating research questions

As mentioned, the objective of the present study was to perform a review to find and identify the available literature relating to key issues surrounding generic medicines in Pakistan. Key issues including the availability, affordability, knowledge, attitudes, perceptions and practices regarding generics including the percentage prescribing of generics versus branded medicines.

Recognizing and generating research questions

The review focused exclusively on all literature available regarding key issues surrounding generic medicines in Pakistan. The research questions developed were:

RQ1: What is the knowledge/awareness, perception, attitudes and practices regarding generic medicines among the physicians, pharmacists, nurses, pharmacy and medical students?

RQ2: What is the extent of access to generic medicines in terms of their availability and affordability in Pakistan?

RQ3: What is the situation regarding WHO prescribing indicators focusing on the percentage of medicines prescribed by their generic names?

RQ4: What interventions/legal procedures are required to enhance the use of generic medicines in Pakistan?

Search strategy

A literature search was performed using Google Scholar® and PubMed. The search strategies were drafted in accordance with the database protocol using search terms related to generic medicine, generic prescribing, generic dispensing, generic medicine policy, knowledge attitude and practice, physician, pharmacist, drug use, Pakistan. These were???

This was followed by evaluation of Expert opinions and Grey literature and related data was also included in this review article. Suggestions related to future research regarding generics in Pakistan were also searched.

Study selection

Potentially relevant studies were identified based on their titles and abstracts. Furthermore, the relevant studies were read with details and were selected in accordance with the eligibility criteria.

Eligibility Criteria

Given the projected scarcity of published literature on this issue, the qualifying criteria were purposefully wide to maximize the sensitivity of the search. A manual search of grey literature was conducted, and relevant references were also included. The population-concept-context framework, as proposed by the Joanna Briggs Institute for scoping reviews, was followed to develop the research selection criteria.

Population: physician, pharmacist, medical and pharmacy students, patients, prescriptions, and drug use registers.

Concept: generic medicine, generic prescribing, generic dispensing, generic medicine policy, knowledge attitude and practice of physician, pharmacist, nurses and students in Pakistan.

Context: Pakistan

Data Charting

We summarized the key research conclusions of each study as well as organized these into a chart using the following topics after we studied the articles and determined their eligibility. The key topics criteria were the first author, year of publication, study design, study population, tool, sample size, study setting, knowledge, attitude, practice, affordability, availability, pricing, generic prescribing percentage and conclusion. These topics were addressed under relevant themes that included: knowledge, attitude, perception & practice of HCPs regarding generic medicines in Pakistan, availability, affordability, pricing of generic medicines, and an assessment of generic prescribing percentages using who core indicators:

RESULTS, FINDINGS AND IMPLICATIONS

Google Scholar and Pub-Med were searched for the period 2000-2023. Papers were analyzed for eligibility including affordability, availability, pricing, generic prescribing percentage respectively. Two researchers (SA, ZS) analyzed the articles thoroughly and disagreements were resolved through discussion with a third (FKH). Both quantitative and qualitative research studies were eligible for inclusion. the selected papers were grouped into different themes. We identified 2150 papers out of which 45 studies satisfied our inclusion criteria (Figure 1).

Knowledge, Attitude, Perception & Practice of Healthcare Givers Regarding Generic Medicine in Pakistan

According to the sourced studies conducted among prescribers, most prescribers favored the use of locally produced generics over branded medicines due to economic considerations. However, their understanding about the potential safety of generics was typically sub-optimal and the term bioequivalence was not typically understood. One study though indicated that physicians are hesitant to prescribe generics due to their perceived low efficacy and potency. Studies also showed that community pharmacists possessed knowledge about generic medicines and that an essential factor in dispensing LPGs was low priced. Encouragingly, pharmacy and medical students

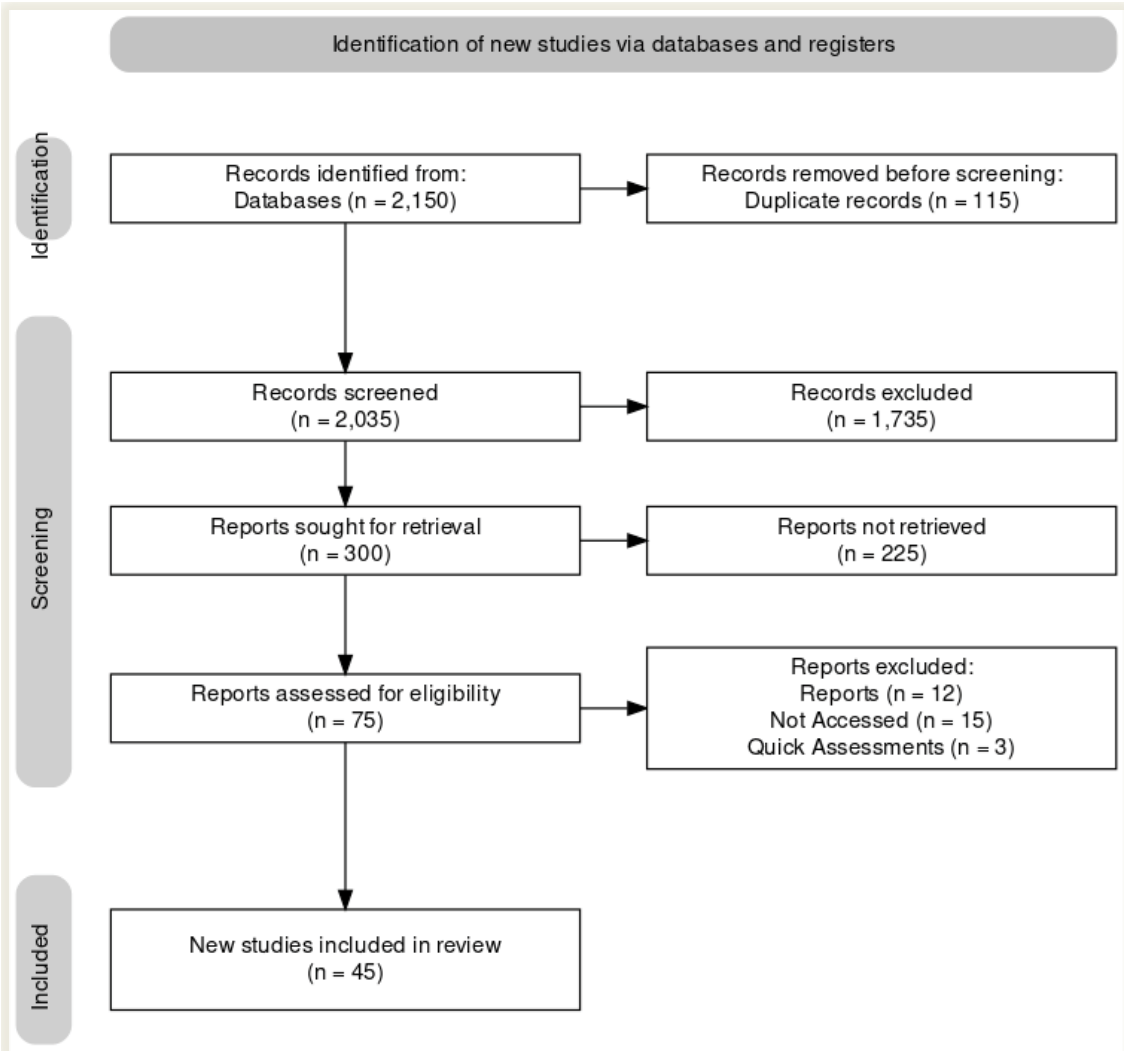

Figure 1. PRISMA-ScR Flow Diagram [61]

typically demonstrated a keen understanding of generic medicine, as well as a positive perception of generic bio-equivalency and the significance of increased use of generic medicines in reducing economic burden. Despite concerns regarding the quality and adverse effects of generic medicines in comparison to the brand-name medications, the majority of the students established a common ground that generic medicines are bioequivalent to the branded ones (Table 1).

Availability, Affordability, Pricing of Generic Medicine in Pakistan

Availability

A number of studies included in this review revealed that the average availability of medicines in Pakistan is low. LPGs were found to be less readily available. OBs were more generally available in the private-sector, leading to the conclusion that patients were compelled to obtain costly OBs in most circumstances, putting patients' affordability at risk. According to one study, increased availability of LPGs could lead to a generic prescribing system, which would increase the availability and accessibility of vital medications. The specific causes of limited availability must be identified.

Affordability

Treatment with LPGs is seen as affordable in a few studies for all income classes, whereas the cost of standard treatment with OBs is typically unaffordable, i.e. more than a single daily wage (1.4 day's wages).

Table 1: Knowledge, Attitude, Perception & Practice of Healthcare Givers Regarding Generic Medicine in Pakistan

Author/year Reference	Study Design	Population & Sample size	Setting	Knowledge/ Understanding	Attitude/ Perception	Practice	Conclusion
Shazia Qasim Jamshed et al. 2010 [62]	Qualitative exploratory study	Community Pharmacists N=8	Karachi	Adequate understanding	Positive perception	Mixed reactions	Presence of professionally qualified pharmacists in community pharmacies is needed to enhance generics use.
Shazia Qasim Jamshed et al. 2011 [25]	Short Report, exploratory ,Qualitative	Dispensing doctors N=11	Karachi	Limited Knowledge	Negative perception due to quality and efficacy issues	Mixed reactions	The reintroduction of Generic Medicine Act could be a positive development.
Shazia Qasim Jamshed et al. 2012 [46]	Exploratory-descriptive study	General Practitioners N= 289	Private clinics in Karachi	Correct Knowledge regarding generic medicine concept but knowledge about safety is not up to the mark.	Positive attitude & perception regarding efficacy of generics and showed interest to prescribe low cost medicine.		The dissemination of generic pharmaceutical information may help to strengthen generic prescribing.
Shazia Qasim Jamshed et al. 2015 [63]	Qualitative and quantitative cross sectional	Final-year pharmacy students N=236	6 pharmacy institutes of Karachi	Poor understanding	Positive perception toward generic medicines.		Pharmacy academia should address the understanding issues regarding generic medicine.
Imran Masood et al. 2016 [64]	Cross-sectional survey	Physicians N=150	Public sector hospitals in Bahawalpur		Majority showed negative attitude regarding generic prescribing due to efficacy issues.	Preferred brand medicines over generic medicines	Their lack of understanding about generic drugs, as well as the effect of pharmaceutical ads, have a substantial impact on their practices.
Usama Asif et al. 2017 [65]	cross-sectional study	Pharmacy & Medical Students N=295(Medical Students= 110. Pharmacy Student=185)	Lahore	Good Knowledge	Positive perception with concerns regarding quality & side effects of generics.		Educational initiatives and generic drug regulations are critically required.
Tauqeer Hussain Mallhi et al. 2022 [66]	Cross sectional survey	Community pharmacists N=528	Punjab	Sufficeint Knowledge	Mostly negative attitude regarding quality and efficacy	Mixed reactions	Inadequate knowledge and negative attitudes significantly affected the practices of the pharmacist. Necessity of promoting generic medicines in Punjab.

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Pricing

It is also advised that appropriate pricing rules be implemented in to enhance the availability, decrease the prices, as well as improve affordability (Table 2).

Assessment of generic prescribing percentages using WHO core indicators

The sourced studies indicated a considerable cause for concern regarding generic (INN) prescribing. A number of studies

Table 2: Availability, Affordability, Pricing of Generic Medicine in Pakistan

Reference Author	Study design	Tool	Population & sample size	Setting	Availability	Affordability	Pricing	Conclusion
Muhammad Rehan Sarwar et al. 2018 [67]	Descriptive, cross-sectional survey	Data collection form	Cancer patients aged ≥18 years N= 4400 patients	22 Cancer hospitals, 44 private pharmacies of Punjab	Fairly high availability for OBs and generally low availability for LPGs. Availibilty was better at private pharmacies	LPGs were more affordable for all income classes.		Government and regulatory authorities must take adequate steps and formulate such policies to ensure the equitable availability and affordability
Anum Saqib et al. 2018 [68]	Descriptive, cross-sectional survey	Data collection form	Cancer patients aged ≥18 years N= 4483 patients	22 Cancer care hospitals, 44 private pharmacies of Punjab	Less availability in case of LPGs	LPGs of both biologics and non-biologics had more affordability.	Most of the patients with cancer were prescribed non-biologics due to their low price and better affordability. Y	Special consideration is required to improve national health policies
Amna Saeed et al. 2019 [44]	Cross-sectional study	World Health Organization (WHO) / Health Action International (HAI) methodology	Public Sector Hospitals N=16 Privvate Pharmacies N=16	Lahore Division,	Poor Availability	Unaffordable with OBs	1.4 day's wages with OBs and 0.6 day's wage with LPGs	Improved availability of LPGs may result in a generic prescribing system, which may boost the availability and accessibility of essential drugs.
Amna Saeed et al. 2020 [48]	Pre-post survey	Modified WHO/Health Action International (WHO/HAI) methodology.	Public Sector Hospitals N=16 Privvate Pharmacies N=16	Lahore Division	Slightly improved in case of OBs and reduced in case of LPGs in public sector.	Standard treatment for some of the most prevalent ailments found unaffordable.		The implementation of NDPP 2018 led to increase in drug prices. The drug pricing policy must be reviewed to ensure access to essential medicines.
Amna Saeed et al. 2021 [43]	Cross-sectional survey	World Health Organization (WHO) / Health Action International (HAI) methodology	Public sector hospitals N=40 40 Retail pharmacies N=40	Eight cities	Poor Availability of CVD medicines in both public & private sector	Both OBs and LPGs were found unaffordable in the private sector		Revision of pricing policies, structuring, and their implementation
Zikria Saleem et al. 2021 [69]	Cross-sectional survey	World Health Organization (WHO) / Health Action International (HAI) methodology	Private Pharmacies N=16	4 regions of Lahore, Pakistan	Availability of Both OB and LPG is less than 50%	Unaffordable Treatment with OB & LPG	Cost with OB is 0.5 day's wage (median) & 0.4 day's wage (median) with LPG	Need for Price control policies to improve availability
Murad Bibi et al. 2022 [70]	Cross sectional descriptive research	World Health Organization (WHO) / Health Action International (HAI) methodology	Public Hospitals N=9 Private Pharmacies=9	Nine districts of Baluchistan province	Mean availability was low for OBs and fairly high for LPGs	Treatment with LPG medications seems affordable	Cost of OBs is exceeding the minimum daily wage. essential LPG medicines are economical when used solely for medication therapy	Policy development regarding pricing regulations and mark-up control is needed in order to increase availability, lower prices, and enhance affordability.

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found that no prescriptions were written using generic names, implying that the WHO standard for prescription formatting is not being followed by a single physician in these studies. Overall, the concept of generic prescribing is a concerning with very limited adherence to a core WHO prescribing indicator. To promote rational drug use, there is an urgent need to implement interventions as per WHO recommendations to educate physicians, pharmacists, and the patients regarding generic medicines. This is endorsed by the finding of a few studies from public sector hospitals which showed that the percentage of drugs prescribed by their generic names was greater than 50%; however, still questionable below the WHO recommendation of 100% generic prescribing. The sourced studies also emphasized the presence of qualified pharmacists from evaluation of prescriptions to dispensing of medicines to help address any queries. Appropriate pricing policies are also required to enhance the rational use of medicines especially in patients with chronic NCDs (Table 3).

BARRIERS WITH IMPLEMENTING A GENERIC PRESCRIBING AND DISPENSING POLICY

Several obstacles to generic prescribing and dispensing implementation were identified in the literature.

Lack of a generic policy in Pakistan

One of the most pressing challenges in Pakistan is the current lack of a generic medicine policy. The Generic Drug Act was implemented in 1972, but it was quickly repealed due to widespread criticism from the commercial sector and the medical community[49]. This Act made it illegal to prescribe pharmaceuticals by brand or patented name, as well as to manufacture and sell medicines under a proprietary name. The government aimed to pit local manufacturers against global corporations to drive down prescription prices. However, prices remained largely unchanged as the focus shifted from cost to ensuring product quality[49,52]. The act was revoked after

Table 3: Assessment of generic prescribing percentages using WHO core indicators

Reference Author & Year	Population & Sample Size	Setting	Generic Prescribing %	Conclusion
Muzammil Hasan Najmi et al. 1998 [71]	Prescriptions N=601	Internal Medicine, Pediatrics and Psychiatry units of 3 Hospitals of Twin cities	23.60%	Prescribers have reservations about the quality & availability of generic preparations
Humayun Riaz et al. 2011 [72]	Prescriptions N=4923	Lahore, Gujranwala, Sheikupura, Sialkot and Kasur	20%	The low percentage prescription of drugs by their generic name is responsible for the high cost of drugs to patients.
Madeeha Malik et al. 2012 [73]	Daily registers, medical records, prescriptions, patient-held records Oct 2010-11	Public and private tertiary healthcare facilities in the twin cities	3%	The prescribing pattern with regard to of adherence and rationale remains low. The impact of pharmaceuticals must be checked.
Ayaz Ali Khan et al. 2013 [74]	Prescriptions N=200	Different areas of Sindh	0%	Even a single prescriber does not use the standard prescription structure. Even for a single prescription, there are no instructions for the pharmacist nor dispensers.
Muhammad Shoaib Akhtar et al. 2013 [75]	Prescriptions N=200	Private GPs in Islamabad	0%	Prescribers are free to prescribe the drugs of their choice either they comply with the national policies or not, this causes a burden on health system
Hanif ULLAH et al. 2013 [76]	Questionnaire N=200	Public and Private Prescribers of Abbottabad	0.13%	Prescribing practices are not being properly followed according to WHO guideline
Rana Shahbaz et al. 2014 [77]	Prescriptions N=355	6 Branches of Community Pharmacy, Lahore	1.70%	Importance should be given to generic prescribing indicator.
H.S. Babar et al. 2014 [78]	Prescriptions N=206	Different pharmacies of Lahore	0.50%	Concept of generic prescribing is negligible and Adherence to WHO core prescribing indicators was also unsatisfactory.

Tuba Siddiqui et al. 2015 [79]	Prescriptions N=100	Two government hospitals, three private hospitals and two outpatients' settings in Karachi,	0%	Educational Training of Physicians for proper prescription writing.
Aqeel Aslam et al. 2016 [80]	Prescriptions N=120	Government hospitals of 4 different cities of province Punjab	39.50%	The situation of rational drug use indicators in the government hospitals is alarming.
Syed Muhammad Ashar et al. 2016 [81]	Prescriptions N=650	Tertiary care hospital, Peshawar	5.40%	Educational interventions and strict compliance to WHO drug policies could play a role in generic prescribing
Humayun Riaz et al. 2016 [82]	Prescriptions N=13693	Healthcare facilities of Punjab and Sindh provinces	21.80%	Low prices for generics, physician education, prescribing guidelines and formularies are needed.
Muhammad Atif et al. 2016 [83]	Prescriptions N=2400	two tertiary care hospitals of Bahawalpur	56.60%	The significant difficulties were polypharmacy, brand prescription, antibiotic over-prescribing, short consultation as well as dispensing times, patients' lack of understanding about prescribed medications, and the inability to have all critical pharmaceuticals in stock.
Muhammad Atif et al. 2016 [84]	Prescriptions N=1000	Primary healthcare centers (PHCCs) of the Bahawalpur	71.60%	It is recommended that there should be continuous education and training of physicians about rational prescribing. pharmacists should be appointed at all PHCCs for proper dispensing of medicines.
Muhammad Atif et al. 2017 [85]	Prescriptions N=1000	ten wards & the Pharmacy Department of Bahawal Victoria Hospital (BVH), Bahawalpur	52.50%	Continuous physician education and training, as well as cost-effective legislation, might all help to promote reasonable usage.
Haya Hussain et al. 2017 [86]	Prescriptions N=400	Institute of Radiotherapy and Nuclear Medicine (IRNUM) Peshawar	2.40%	Inappropriate prescription practices leading to health and economic issues. Presence of clinical pharmacist to evaluate prescription.
Haya Hussain et al. 2017 [87]	Prescriptions N=200	Leady Reading Hospital, Peshawar	0%	Pharmacists should be hired and a medication review system is required.
Sidra Mehmood et al. 2018 [88]	Prescription: Between 2010-2015	Tertiary care hospitals and private practitioners.	21.40%	Issues of international non-proprietary name prescribing need investigating along with the high number of medicines per encounter and gender inequality.
Muhammad Atif et al. 2018 [89]	Prescriptions N=300	private clinical practices of Bahawalpur	23.30%	Continuous education and training of physicians regarding the rational prescribing of drugs and presence of pharmacists is required.
Zakir Khan et al. 2019 [90]	Prescriptions N=703	Geriatric Medical Outpatient Department and Emergency Ward of tertiary care teaching hospital at Islamabad,	30%	The major identified problems were polypharmacy, low generic prescribing, over-prescribing of antimicrobials and injectable.
Zakir Khan et al. 2019 [91]	Prescriptions N=586	Two teaching hospitals of Islamabad	13.50%	The key issues highlighted were antibiotic overuse, poor generic prescription, and lengthy dispensing delays.

Muhammad Asim Farooq et al. 2019 [92]	Prescriptions N=300	Pharmacies and hospitals located in Lahore	0%	Need to improve the knowledge about prescription writing and prescribing practices
Talha Khalid et al. 2020 [93]	Prescriptions N=2262	Jinnah Hospital Lahore	89%	Appropriate utilization of EMs not only assures their availability around the clock, but also decreases budgetary burden on public sector hospitals.
Haiqa Hafeez et al. 2020 [94]	Prescriptions N=2000	OPDs of two tertiary care centers of Lahore,	0%	Implementation of WHO-recommended treatments including patient, pharmacist, and physician education to promote rational medication use. Each hospital must have a pharmacist on staff. .
Khayal MUHAMMAD et al. 2021 [95]	Prescriptions N=639	OPD of Teaching Hospital, Islamabad	6.10%	The pharmacotherapy pattern amongst consultants addressing WHO core prescription patterns deviates from the WHO recommendations. Qualified pharmacists are required in all healthcare settings, from monitoring through medicine distribution.
Sohail Kamran et al. 2021 [96]	Prescriptions N=296	Tertiary care hospital of Peshawar	5.70%	Observed low generic prescribing
Saman Omer et al. 2021 [97]	All prescriptions from Aug-Oct 2020	Public health facilities in district Mirpur, Kashmir	2%	A multi-disciplinary approach involving authorities, industry and professionals is required to promote rational prescribing.
Mateen Abbas et al. 2021 [98]	Prescriptions N=2290	Secondary healthcare hospital of Islamabad	4.80%	Polypharmacy, usage of a brand name, antibiotic overuse, and prescription legibility and completeness are all frequent non-compliant prescribing practices.
Najia Rahim et al. 2021 [99]	All prescriptions from Dec 2017-Feb 2018	Pediatrics in-patient departments (IPD) of two government hospitals of Karachi	3%	Brand name drugs were the choice of the majority of pediatricians.
Waseem Mehmood et al. 2022 [100]	Prescriptions N=200	Teaching Hospital, Swat	12.47%	Shows deviation from the standards guidelines of WHO
Jamil Ur Rahman et al. 2023 [101]	Prescriptions N=86	Medical ward of Khyber Teaching Hospital, Peshawar	3.61%	Prescription pattern and prescription errors have highlighted the necessity to build an accurate system

38 local pharmaceutical companies had been found guilty of manufacturing substandard medicines[102] and new The Drugs Act 1976 stated that "Single-ingredient drugs shall be registered generally by their generic names while compound drugs shall be registered generally by their proprietary names". However, in the new act no policy is mentioned regarding prescribing of generic medicine[103].

Implementation of pricing policies

Pricing policies for generics in comparison to an innovator's brand are also required and in some cases generics are registered at higher prices than the innovator's brand[54]. Whilst in 2018, DRAP issued a pricing policy for generics. However, despite this prices of the same generics (branded generics) in Pakistan are not the same. Even after implementing a generic prescribing policy, there is a still a considerable likelihood that affordability will be a concern unless re-visited[102].

Lack of bioequivalence studies

It is also observed there was a lack of published bioequivalence studies and unrestricted branded generics are barriers as generic medicines are currently registered in Pakistan as BGs without bioequivalence tests. This results in a significant number of multiple sourced medicines being made available[104]. However, this is an identified concern since, as mentioned, generics are currently exempted from bioequivalence studies as per the registration process of DRAP. This has resulted in physicians' preference for branded drugs over generics due to their perception of branded drugs' high efficacy potential[64]. Evidence of bioequivalence (two drugs are regarded bioequivalent if their availability in the human body does not differ significantly) for generic medications should be considered a criterion for marketing authorization. Furthermore, focusing on WHO prequalification of manufacturers and laboratories would benefit access to quality assured generic medicines[102].

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This should be progressed under the Lome agreement across LMICs[105].

Absence of qualified pharmacists and electronic record system

The absence of qualified pharmacists operating in community pharmacies is also a major concern as most retail pharmacies in Pakistan, particularly in urban areas, are run by unqualified people (non-pharmacists), who are usually uneducated beyond a secondary school certificate[54].

In addition, because most medicine retail stores in Pakistan lack an electronic record keeping system, patients could obtain a different company's branded generic each time they refill their prescriptions, which may have a negative impact on patient outcomes if there is confusion among patients[6]. The mandatory presence of pharmacists in community pharmacies as well as their improved coordination with other stakeholders, particularly prescribers, is critical to the safe implementation of generic prescribing policy[102]. Encouraging INN prescribing will help as well; however, the acceptable quality of generics must be guaranteed to enhance the implementation of such policies. A first step is that the Government of Punjab has established legal requirements for the presence of qualified pharmacists at pharmacies in the Punjab Drug Rules 2007 (PDR-2007)[106].

Other barriers

To assure efficacy and safety with the innovator's product, generic medicines must meet a higher standard than is currently the case. DRAP), like those of many other drug authorities of LMICs, has yet to enforce these criteria[54]. This is not helped by DRAP registering 6440 medicines in 2018, and now 76,000 brands of around 1600 medicines and combinations are available in the country[104].

DISCUSSION

We believe this is the first study to fully consider all pertinent aspects related to generic medicines in Pakistan. We have reviewed studies including knowledge, attitude and practice of HCPs as well as included studies regarding the affordability, availability and pricing of generics in Pakistan. In addition, current rates of prescribing of generics (INN) versus branded generics and originators in Pakistan.

According to studies conducted among prescribers' mix reviews were found. Encouragingly, the majority of the physicians in identified studies had correct knowledge about the concepts surrounding generic medicines. However, their knowledge about their safety was lacking, and the word bioequivalence was not understood. Physicians indicated that brand name medicines, including branded generics, were of greater quality than generics as that they had to meet higher safety standards and with a fewer side effects. They believed that generic medicines were therapeutically similar to branded drugs. However, generics were typically seen as less safe and only locally renowned manufacturers produced safe generic medicines. Because of lower prices, a number of prescribers encouraged the use of locally produced branded generics over brands, including originators, manufactured by multinational companies. This will help with issues of affordability; however, more policies are needed to obtain lower routine prices for essential medicines in Pakistan. Having said this, gaps were identified in generic medication knowledge among their prescribers[25,46].

Table 4: Summary of Challenges & Recommendations

Sr. No	Challenges	Recommendations/ Research Areas
1	Generic drugs can be registered without bioequivalence studies	· There is need of bioequivalence regulations/studies for generics.
		· Strict regulations regarding drug registration should be implemented by Drug Regulatory Authority of Pakistan.
2	High number of generic drugs being registered in the country	· Proper policy/implementation for drug registration
		· Regulations are required for unrestricted registration of Branded generics
3	Implementation of Pricing Policy	· Implementation of pricing policy for newly registered drugs
		· Implementation of pricing policies for generics with comparison to an innovator's brand
4	Need of Generic Policy	· Government should redevelop Generic Act or Policy to start initiative of generic prescribing and dispensing
		· Need for basic research regarding barriers related to generic dispensing and prescribing INN
		· Research is required to assess concerns about previous Generic Act
5	Limited Awareness/ Knowledge	· There is need to educate health professionals regarding basic concepts related to generic medicines, bio-equivalence as well as safety and efficacy of generics.
		· Awareness of consumers and masses about generic medicine
6	Presence of Qualified Pharmacists	· Operating of all pharmacies under the direct supervision and presence of registered pharmacists
		· Policies to make compulsory that all prescription drugs are dispensed on the prescription of registered medical practitioner and must be dispensed by a licensed pharmacist
		· Incentive policies for pharmacist dispensing generics

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One published study concluded that physicians prefer branded medicines over generic medicines, because of their better efficacy potential[64]. This was similar to a study from Iraq where physicians on the whole, have negative perceptions and attitudes towards generics and locally produced drugs. Significant gaps in physician knowledge and perceptions of generic drugs were observed in the study from Iraq, particularly in terms of efficacy and safety[107].

The published studies in our review also demonstrated that community pharmacists were aware of generic medicine concept as well as supported the use of locally manufactured brands. There were though mixed responses to dispensing of locally produced medications; however the key factor to dispense LPGs was low cost[62]. Mohammed et al. (2020) in their study in Ethiopia also found that while over fifty percent of respondents recognized the importance of generic medicine, which include their right to carry out generic replacement, and possessed a positive attitude regarding generics, a gap was identified in community chemists' understanding of and views regarding generics as well as brand drugs[108]. A study from China also discovered gaps in respondents' generic substitution knowledge and views. Pharmacists who were better knowledgeable about generic medications were more likely to be supportive of generic substitution. Whilst it appeared that Chinese pharmacists would mostly accept generic substitution, they were also concerned about the dependability and quality of generic medications similar to the situation in Pakistan[109]

Encouragingly as well, pharmacy and medical students showed good understanding of generic medicines and exhibited a good perception towards the bio-equivalency of generics and their role in lowering the costs of medicines. Despite concerns about the quality and side-effects of generic drugs as compared to brand-name medications, the majority of students also agreed that generic drugs are bioequivalent to brand-name drugs. They disagreed that generic medicines are of lower quality and less effective than brand-name medicines[63,65]. This is similar to the situation in India where Manasa, et al. (2020) found that most of the medical students surveyed believed that generic drugs were non-inferior to branded drugs and had good understanding about generics[110]. Another study from Greece also found that final year pharmacy students were mostly aware that generics were the same active substance as brand-name products but less expensive. However, they had concerns regarding their safety and efficacy of generics. Having said this, the majority of students in Greece agreed that pharmacists should probably recommend the use of generics[111].

According to WHO, UHC means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. UHC can only be achieved when there is affordable access to safe, effective and quality medicines and health products. A study performed in Baluchistan also showed low availability of OBs[70]. According to one study, LPGs were more readily available in the public sector than OBs; however, in the private sector, OBs were more commonly available than LPGs. Since the overall availability was better in the private sector, it is possible to conclude that patients were required to acquire expensive OBs in the majority of situations, putting patients' affordability at risk[43]. This is similar to a study in China where there were concerns with availability of medicines including generics in the public and private sectors[112]. Another study from China found that access to important medications for children is limited by a lack of supply. The mean availability of both originator brands (OBs) and low-cost generics (LPGs) in the public sector was 7.5% and 34.2%, compared to 8.9% and 29.4% in the private sector, respectively[113].

A study also indicated that increased availability of LPGs may lead to encouraging a generic prescribing system, which may boost the availability and accessibility of essential drugs[44]. However there is a need and potential to improve understanding of generic medicines in Pakistan's healthcare sector similar to other countries[114]. There could be achieved by addressing a variety of factors including the poor availability of medicines generally enhanced by an underestimation of demand, delays in processing drug orders, and budgetary constraints. However, more in-house assessments are required to identify the particular causes of low availability before we can say anything with certainty[44]. According to the published studies, policy enhancement addressing pricing laws and mark-up control is also critical in Pakistan to increase availability of medicines at lower prices to improve their affordability.

Most of studies expressed that treatment with LPGs is acceptable for all income classes in terms of affordability[44,67,68,70] whereas Saeed et al. [year] found that the cost of standard treatment with OBs was unaffordable, i.e., more than a single daily wage (1.4 day's wages) and the cost of LPGs medicine required to purchase the standard treatment of the selected diseases was only 0.6 day's wage (median), i.e. below a single daily wage[44]. However, still unaffordable if patients are on multiple medications as seen with NCDs such as diabetes. A similar outcome was found from a study conducted in Afghanistan where a wage of less than one day was enough to afford one-month's supply of generic medicines at the lowest price[115]. However, again dependent on whether patients had chronic NCDs requiring multiple medicines

A study by Bibi et al., also showed that standard treatment cost with OBs is considerable exceeding the minimum daily wage. However, treatment with LPGs appeared affordable. Furthermore, essential LPG medicines were economical when used solely for medication therapy[70]. Saqib et al. also found that most of the patients with cancer were prescribed non-biologics due to their low price and better affordability. In contrast to OBs, LPGs of both biologic and non-biologic anticancer medicines had less availability but greater affordability[68]. A few studies also highlighted that in Pakistan treatment with both OB and LPG was unaffordable[43,69] consistent with a study from Jordon where the treatment of hypertension either by LPGs or OBs cost more than 1-day income by lowest paid unskilled government employee[116]. These issues need to be urgently addressed in Pakistan if the Government is to reduce the current burden of NCDs in the country.

However, a current concern to increasing the prescribing

of LPGs is that a number of the sourced studies showed 0% prescribing by INN Consequently, a considerable need to educate physicians, pharmacists, and patients in order to promote rational drug use[74-76,78,79,87,92,94]. Approximately same results were expressed in a study from India that even in rural India, brand name prescribing predominates. This study also came to a conclusion that WHO drug usage indicator criteria must be disseminated, and individual community-based clinician prescription practices must be consistently monitored in terms of INN prescribing patterns[117].

Only a few studies from public sector hospitals showed that percentage of drugs prescribed by generic names was more than 50% which is even though less than optimal value of 100%. These studies found that physicians should be educated and trained on rational prescription on an ongoing basis. The key barriers discovered were polypharmacy, brand prescription, antibiotic over-prescribing, and patients' lack of information about given medications. Cost-effective pricing policies could play an important role in promoting the rational use[83-85,93] with studies from Tanzania finding for instance that 84.4% of medicines were prescribed by INN[118].

A number of studies also recommended hiring of qualified pharmacists in all healthcare setups from monitoring to dispensing of drugs to enhance the dispensing of LPGs.

Strengths and limitations

Literature Retrieval: In this review we restricted publications to being in English, published in a journal, and available electronically at the Faculty of Pharmacy, Baha ud Din Zakariya University, Multan, Pakistan. As a result, we may have overlooked significant studies. One shortcoming of the scoping review process is that no evidence quality evaluation was performed. However, we used the considerable experience of the co-authors to assist with this as we knew some studies would be published in Journals not cited in Pub med or Web of Science and some would be sourced via the internet.

CONCLUSION

The current state of generic medicine in Pakistan is critical, marked by insufficient prescribing practices despite adequate knowledge among healthcare providers. The negligible rates of generic prescribing highlight the urgent need for systemic reforms. Addressing affordability and access to essential medicines remains a significant challenge. To improve the landscape of generic medicine, it is essential for the government to revisit and strengthen The Drugs (Generic Names) Act of 1972, aligning it with global best practices. Implementing robust bioequivalence regulations is crucial to ensure the safety and efficacy of generic medicines. Additionally, educational interventions targeting healthcare professionals, along with strict adherence to WHO drug policies, will enhance awareness and compliance. Establishing qualified pharmacists and integrating electronic health systems at all levels of care are vital steps toward better healthcare delivery. Furthermore, the lack of generic medicines identified by International Nonproprietary Names (INN) underscores the need for action.

AUTHOR CONTRIBUTIONS

"Conceptualization, S.A. and Z.S.; methodology, F.K.H and B.G.; software, S.A.; validation, A.C., B.G. and Z.U.A.; formal analysis, M.S.A and B.G.; investigation, T.E.A.; resources, W.M.A.; data curation, A.H.; writing—original draft preparation, S.A and Z.S.; writing—review and editing, Z.S., F.K.H and B.G.; visualization, M.T.I.; supervision, A.C and B.G.; project administration, Z.S and F.K.H.

CONFLICTS OF INTEREST

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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