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REVIEW

Generic Medicines as A Way to Improve Access and Affordability: A Proposed Framework for Pakistan

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ABSTRACT

Medicines play an important role in health systems throughout the globe; however one third of the world population does not have access to essential medicines. Generic drugs have been instrumental in reducing cost and improving affordability. Generic penetration varies in the developing world and the sale of generics are growing in all the major markets, but the proper domestic availability of generics and their quality use is still a question mark. With the increasing population and shrinking resources, generics could be a recipe for improving the access to and affordability of medicines in Pakistan. However, to gain a wider health professionals' support, it is vital to understand the issues surrounding generic medicines.

This proposed strategy will document the relative importance of the acceptance of generics in Pakistan. This attempt will ameliorate the perception and credibility of generic drugs among providers, prescribers, and consumers. Moreover, this effort will provide the baseline data to assist policy makers to promote the quality use of generic drugs.

Key Words: Generic Medicines, Pakistan, Drug Policy, Pharmaceutical Industry

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Introduction

Developing countries possess inefficient and inequitable healthcare systems characterized by bare resources, economic instability and disparity and meager infrastructure. These are the major obstacles in providing access and affordability to quality healthcare. Access to and affordability of medicines is a vital issue in any Asian region and Pakistan, whose healthcare systems being encrusted with multitudinous challenges along with accelerating healthcare cost, is not an exception in terms of access and affordability. As 77% of medical expenditure in Pakistan is out of pocket[1], the issues of access and affordability need to be addressed by the induction and practice of generic medicines, a major cost containment strategy worldwide.

Generic Medicines and Innovator Brands

The term 'generic product' is used in different ways. It can be a product that is marketed under the drug's non-proprietary approved name, or it can be a product that is marketed under a different brand (proprietary) name. It is sometimes used to refer to any product from a company other than the innovator (research-based) manufacturer [2].

A common use of the term that used by the World Health Organization WHO [3], is for a pharmaceutical product that is intended to be interchangeable with the innovator product in an individual patient, which is usually manufactured without a license from the innovator company, and marketed after the expiry of the patent or other exclusivity rights.

An innovator product is a medicinal product that is authorized and marketed on the basis of a full dossier i.e. which receives the marketing authorization first and which is usually the patented version of the medicine. Three determinants of quality, safety, and efficacy apply to generics similarly, as in case of an innovator product.

Thus, a brand-name drug and its generic counterpart are chemically the same and generic drugs are also regulated by the FDA, requiring the same guidelines as their brand-name counterparts. Thus, the incorporation of generics which is one of the major cost containment strategies[4] is in need of time.

Perception of Generic Drugs

According to the WHO, 30% of the world's population still does not have regular access to essential medicines. 74% of AIDS medicines are still under monopoly (under patents). 77% of Africans still have no access to AIDS treatment. The access to medicines in developing countries relies primarily on affordable generic versions of patented medicines [5].

Several studies have been conducted so far in Western countries regarding the perception and acceptance of generic drug use in health professionals. A study conducted in France shows that prescribing by INN is generally favourably accepted by those in the health area, with a concern for adverse effects [6], [7]. Likewise, in Brazil, the generic drugs are known by many, but used by only a few[8]. In Slovenia, general practitioners, being concerned about the cost of prescribed drugs, showed willingness to increase generic drug use [9]. Currently, in countries like Australia, the utilization of generic medicines is a tool for lowering the cost of health care. Generic prescribing, generic dispensing and generic substitution are being strongly supported by health authorities in many countries including Australia [10].

A considerable body of evidence suggests different policy tools to promote the use of generic medicines in industrialized countries like Canada, Denmark, Germany, the Netherlands, the United Kingdom, and the United States. Policy manifestations from these countries encompass both the supply-side and demand-side measures that are of essence for generic promotion and generic use [11].

India is one of the leading exporters of generic medicines, with 67% exports going to developing countries. This reflects a buoyant future for generics worldwide [12]. About 60% of all people currently receiving antiretroviral (ARV) treatment in developing countries rely on India's generic medications.

Pharmaceutical Scenario in Pakistan

The Islamic Republic of Pakistan has an approximate population of 158 million [13] with a population growth rate of 2% per annum [14]. As far as the demographic potpourri is concerned, the population is an amalgam of native people with rich cultural and linguistic diversity. With its four administrative provinces, Sind, Punjab, Balochistan and N.W. F. P., the population is clearly depicting an uneven appearance in distribution. In the eastern provinces of Punjab and Sind, there is an estimated population of 78.6%, while Balochistan, though occupying 44% of the total land area of the country has only 5% of its population. In terms of socioeconomic development, Pakistan is overall towards the lower side, but in the past few years, the country has tasted rich economic growth with a GDP growth of 8.4% in 2005 [15].

The pharmaceutical industry in Pakistan is worth around US $1.18 billion, depicting a yearly development of 9.4%. In a number of over 400 registered pharmaceutical companies in Pakistan, there are about 30 multinationals enjoying over 53.3 % of market share, while the rest (46.7%) is in the hands of national pharmaceutical units [16],[17].

With strong influence on the health sector as well as being a key generator of foreign exchange, the pharmaceutical sector of Pakistan has full potential to hike exports to more than $600 million by 2010 [18], but still the sweeping performance of the pharmaceutical industry and the miserable health indicators of Pakistan appear to have a frail liaison with each other. Although the market of pharmaceutical industry is expanding at the rate of 20 per cent annually, about half of the population so far, has no access to modern medicines [19].

Access and Affordability In The Light Of Generic Drugs in Pakistan

In an Asian region which enjoys the largest share of the world's population, access to and affordability of medicines is a critical issue. The phenomenon of globalization has exercised a strong influence on health care. An upsurge in any nation's health care costs is not a matter of a single entity. This is related not only to ageing population but also to interchangeability of prior cheaper molecules into newer ones. In connection to the rising cost of drugs in Pakistan, access and affordability is a debatable issue. The National Drug Policy of Pakistan outlined the availability and accessibility of essential drugs to all strata of society, but what remains the cardinal challenge, is the lack of implementation.

Although around one-third of the pharmaceuticals for Pakistan's total consumption are imported, the manufacturing and marketing of cheaper new generic drugs by national companies are the external economic drivers [16],[17. Recently, the Government of Pakistan has highlighted the importance of generic drugs in context with the marketing and sale of medicines under their generic names to check the prices of drugs [20],[21]. This raises important questions regarding the hesitancy of the use of generic drugs in the prescription, their lack of substitution by the druggist or the pharmacist and the irresolute behaviour of the consumer towards generics.

Dated back to history, there was a failure of legislation which accounted for mandatory generic prescription. This act of the Government was transformed into sound defeat by intentionally creating doubts regarding the quality and efficacy of generic drugs [22]. Although standard drug testing lab is the need of time, a study conducted at the University of Karachi in 2004 suggests that all generics were found analogous with respect to pharmacokinetic behaviour, in-spite of having different excipients, concentration of excipients, sources of raw materials, manufacturing processes, machinery, resources, and also inter individual variations of the study. Results of the study also undoubtedly advocate that generics manufactured in different manufacturing units of Pakistan are near to the standard formulation and produce comparable results [23], but in spite of this, the availability of generic equivalents in the retail pharmacies of Pakistan raises questions. In a report compiled by the "Network for Consumer Protection", the availability of brand products are much more rampant in retail pharmacies than generic equivalents in Pakistan. Not only is this trend of brand product dominance in retail pharmacies observed, but frequently, a large gap exists between brand and lowest price generic availability. As per reports, several contributory components may account for this disparity. Whether this may be necessitated by the patient or postulated as the prescribing and dispensing habits of doctors and pharmacists, it is a cause of grave concern. These stakeholders preferably opt for innovator brands, presumably related to the local marketing practices of manufacturers. Moreover,

false intuitions and beliefs regarding the quality of generics and ignorance or deficient know-how about generics may be some other contributory factors [24]. As pointed out by DFID, there is no ordinance or authoritative rule in terms of generic prescribing or substitution, both in the public or private sector and thus, generic prescribing or substitution is solely on the discretion of the prescriber or dispenser. There is not only the absence of financial incentives for the prescriber and the dispenser, but there is no rebate both for the innovator or generics in either the public or the private sectors [25].

In a nutshell, generic medicines will serve as an important tool to promote access to and the affordability of medicines in Pakistan and the practice and utilization of nonproprietary nomenclature should be highlighted and promoted, not only to arrest unnecessary costs, but to abbreviate the conceivable prescribing errors as well. Thus, to construct a magnanimous generic market in Pakistan, a combination of strategies such as generic-backed legislation and regulation with dependable quality assurance, as well as professional and public acceptance along with economic incentives will be sought.

TRIPS and Pakistan

In fact, the TRIPS agreement obliges all WTO member countries to accord patents on medicines, but still there is flexibility in this regard. As per the TRIPS agreement, each member country reserves the right to have its own specific format on patents. In fact, the Doha Declaration on TRIPS and Public Health clearly penned down that the TRIPS agreement can and should be represented and enforced according to the WTO Member's right to safeguard public health and specifically to promote easy access to all [26]. Pakistan is a part of the TRIPS agreement, and since 2000, the Intellectual Property Legislation is duly positioned.

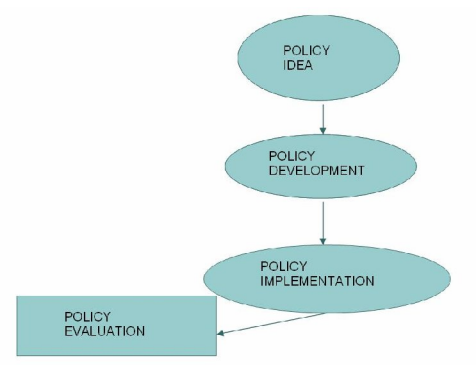
Thus, developing countries are not bound in any way and have the full right to carve and implement their patent laws, taking full consideration of their respective public health needs. But still what remains the cardinal challenge, is the lack of implementation of the flexibilities of TRIPS with regard to the access of medicines.

Recommendations

The accessibility and utilization of generic medicines will gain momentum through a systematic plan of action. The said strategy is likely to perform

- The evaluation and identification of latent factors and circumstances for the physicians and pharmacists in prescribing and dispensing generic medicines
- The advocating of the generic prescribing and dispensing in relation to price and affordability
- sensitization of the consumer in relation to the accessibility and satisfactoriness
- educational outreach to consumers, future practitioners and pharmacists
- Contouring and streamlining the registration process for pharmaceuticals to ensure high-quality standards for generics.

As shown in [Table/Fig 1] a plan for generic medicine policy is recommended, which will later develop into a full generic medicine policy, leading to policy implementation and evaluation.



[Table/Fig 1] A plan for generic medicine policy is recommended, which will later develop into a full generic medicine policy, leading to policy implementation and evaluation.

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