ANALYSIS OF GLOBAL POLICIES ON GENERIC MEDICINES

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Nana Shashiashvili
Associate Professor, Tbilisi State Medical University,
E-mail: n.shashiashvili@tsmu.edu

Natia Kvizhinadze
Associate Professor, Tbilisi State Medical University
E-mail: n.kvizhinadze@tsmu.edu

Nino Bakradze
University of Bremen, Germany
E-mail: Bakradzenino12@gmail.com; Ninbak@uni-bremen.de

RESUME

Access to generic medicines plays a critical role in reducing healthcare costs and ensuring the availability of essential medications for the population. This article reviews global policies, regulations, and approaches that promote the distribution of generics across different countries, as well as the barriers to their circulation, such as stringent regulatory frameworks, negative public perceptions, and market dynamics. Using Georgia as a case study, the analysis examines local regulations aimed at increasing competition by encouraging the use of generic medicines and reducing their prices. The cost advantage of generics enhances their competitiveness and accessibility for consumers. Support from healthcare professionals, raising public awareness, and refining state regulations contribute to the rational use of medicines. Considering these factors, the article highlights the necessary measures required at both global and local levels to improve the accessibility of generic medicines and optimize healthcare expenditures.

Keywords: Bioequivalence, Drug affordability, Generic medicines, Healthcare costs, Pharmaceutical market.

INTRODUCTION

The World Health Organization (WHO) defines a generic drug as a pharmaceutical product commonly intended to be interchangeable with an innovator product manufactured and sold after the expiration of a patent or other exclusivity period. A generic drug is identical to its respective innovator drug in terms of safety, quality, efficacy, dosage form, strength, and route of administration, serving the same therapeutic purpose. While the active ingredients in generic medicines are the same, the excipients (i.e., inactive ingredients) and other aspects, such as shape, color, and packaging, may vary between products.

WHO estimates that at least 30% of the world's population lacks regular access to essential medicines, with this figure rising to 50% in the poorest countries of Africa and Asia. One of the most significant barriers to medicine accessibility is high cost. Promoting the use of generic medicines is crucial for improving access to medications, benefiting both governments and individuals who must pay for medicines out of pocket. Additionally, generic medicines serve as more affordable alternatives to innovative drugs and play a key role in reducing the prices of both brand-name and other generic equivalents.

To effectively implement key policies, various countries have introduced additional policies and initiatives. Barriers to the use of generic medicines vary across regions, ranging from negative public perceptions to the lack of consistent policies. Key facilitators include improving access to information for healthcare professionals and patients, establishing brand interchangeability guidelines for both groups, and implementing regulations that support pharmacists in substituting and promoting generics. In recent years, many governments have actively advocated for the use of generic medicines to contain rising healthcare costs by introducing various policies, initiatives, and strategies [1].

DISCUSSION

Today, generic drugs account for approximately 50% of the European market. Manufacturers considering entering the European market should have substantial knowledge of the pharmaceutical industry. Deloitte has analyzed the European generics market and developed insights for small and medium-sized companies aiming to successfully develop and implement an effective market entry strategy.

In general, generic drugs are sold at lower prices, and there is a public interest in bringing them to market quickly. However, like any scientific and regulatory process, the approval of a generic drug takes time. The FDA requires sufficient time to review the complex information needed to demonstrate that a specific generic drug can be safely substituted for the brand-name drug it replicates. The evaluation period depends on the complexity of the product and the completeness of the application.

Both brand-name and generic drug applications submitted to regulatory bodies must demonstrate the following:

- The generic drug is pharmaceutically equivalent to the brand-name drug.
- The manufacturer can produce the drug correctly and consistently.
- The active substance is the same as in the brand-name drug.
- The correct amount of the active substance reaches the intended site in the body to produce the desired effect.
- The inactive ingredients are safe.
- The medicine maintains stability for a specified period.
- The packaging form is appropriate for storage and distribution.
- The labeling complies with regulatory requirements.
- The relevant patents or legal exclusivity periods have expired.

Dr. Joel Lexchin notes that the availability of generic medicines can lead to significant price reductions and cost savings in both developed and developing countries. One of the primary factors influencing price reductions is the level of competition in the generic market. In the United States, a single generic competitor results in only a 6% decrease in the brand-name drug's price. However, with two competitors, the price drops by 48%, and with nine competitors, it decreases by 80% [2,3,4].

Regarding safety perceptions, a higher percentage of doctors (28.54%) and pharmacists (25.44%) believe that generics are less safe than brand-name medicines compared to the general public (17.97%). The study found no significant differences between the percentage of doctors and pharmacists who had knowledge of generic medications. In terms of side effects, 24.43% of doctors believed that generic drugs are more likely to cause side effects than brand-name medications, while the percentages were lower among patients (18.76%) and pharmacists (20.06%).

Luca Galeli, Katherine Paleria, Antonio de Vuone, and others discuss the safety and efficacy of generic medicines compared to brand-name drugs. They confirm the equivalence of generics to branded drugs when they contain the same active substance, have the same pharmaceutical form, share the same thera-

peutic indications, and demonstrate similar bioequivalence to reference drugs [5].

According to Italian law, generic medicines are considered equivalent to brand-name drugs if they contain the same active ingredient (with a margin of variation of up to 5%), have the same pharmaceutical form, the same therapeutic indications, and similar bioequivalence (within a 20% range) compared to a reference medicinal product.

Theoretically, generic drugs should demonstrate comparable efficacy to branded drugs, as they exhibit physiologically similar properties and therapeutic outcomes. The U.S. Food and Drug Administration (FDA) approves oral generic drugs that show no significant differences from their brand-name counterparts.

However, while generics are assessed for bioequivalence to innovator drugs within a specified range, they are not always therapeutically identical to brand-name drugs [6].

To examine global efforts in promoting the use of generic medicines, an analysis was conducted across eight selected countries: the United States (USA), the United Kingdom (UK), Sweden, Finland, Australia, Japan, Malaysia, and Thailand. The selection of these countries was based on specific factors. The **U.S.** was chosen because generic substitution is a widely accepted practice. The **UK** was included as prescribing generics is a standard procedure. **Finland**and **Sweden** were selected due to their successful implementation of mandatory generic substitution policies.

In the **Asia-Pacific region**, Australia and Japan were examined because both countries have implemented multiple policies related to generic medicines, making their experience relevant for other nations. Malaysia and Thailand were also included as they lack a consistent policy on generic drugs, allowing for a comparative evaluation of challenges and opportunities.

This review was based on extensive information obtained from multiple electronic databases and search engines, including PubMed, Medline, ISI Web of Knowledge, Scopus, ScienceDirect, Springer Link, ProQuest, EBSCOhost, Google Scholar, and Google. The findings revealed significant variations in generic medicine policies. For example, generic substitution is **encouraged** in the U.S., **legally prohibited** in the UK, and **mandatory** in Sweden. Due to these substantial differences, a direct comparison between the countries was not feasible. Instead, each country's experience was analyzed narratively, with an emphasis on fundamental policies [7].

In 53 studies (including 24 from Europe, 10 from North America, 6 from Asia, 5 from Australia and New Zealand, 5 from the Middle East, 1 from Africa, 1 from Latin America, and 1 from the Caribbean), misconceptions about generic medications among patients and drug users were observed. In many countries, a significant number of patients held unfavorable opinions and uncertainties regarding generic medications, which were considered major barriers to their adoption and use.

Studies focusing on specific patient groups (such as those with epilepsy, psychosis, or kidney disease) revealed even more negative attitudes and greater resistance to generic medication use. Several factors have been identified as key influences on a patient's decision to choose generic or brand-name medicines, including:

- The type and severity of the medical condition,
- Professional recommendations,
- Price differences (e.g., cost savings),
- Previous experience with generic medications, and
- General knowledge about generic drugs.

Patients and drug users generally tend to prefer recognizable brand-name medicines over generics. Moreover, in many countries, a significant proportion of patients and consumers still lack sufficient

knowledge or information about generic medications. Educational initiatives are needed to inform patients about the safety, efficacy, and affordabilityof generics. Doctors and pharmacists play a crucial role in promoting the use of generics, guiding patients in their medication choices, and facilitating brand-to-generic substitution [4].

Compared to other developing countries in Southeast Asia, Malaysia has a lower adoption rate of generic medicines, primarily due to insufficient public awareness about their availability and alternatives. Cost savings on medications are particularly important in developing countries (such as Malaysia), where generic drugs are up to 80% cheaper than innovative brand-name medicines. However, despite the government's efforts to regulate and promote generics through the Ministry of Health, pharmaceutical costs have continued to rise, particularly in private medical institutions.

While generic medicines are required to meet safety and efficacy standards, they are not always perceived as therapeutically equivalent to brand-name drugs. However, this perception does not always align with actual price differences, as brand-name drugs may still be marketed at a higher cost despite their generic counterparts being available [8].

In some cases, the **cost of generic medicines** has increased by more than **100%** compared to **innovator brand medicine** in the private sector. A **comparative analysis** of drug pricing studies in developing economies, such as **India and Malaysia**, has highlighted this issue. **Low awareness and limited knowledge** about the **bioequivalence and safety** of generic drugs—among both **doctors and patients**—have contributed to the **complexity of generic drug consumption and preferences**. This lack of awareness also limits **price control mechanisms** in the healthcare industry, posing **a significant challenge** for **self-paying patients** who bear the full cost of their medications.

In **Malaysia**, a survey of **doctors in private medical facilities** found that **most respondents were more likely to recommend brand-name medicines** over generic alternatives. Although **a national policy** was introduced to **promote the use of generics** among both **consumers and healthcare professionals**, the **lack of necessary regulations and enforcement mechanisms** has hindered efforts to **transition from costly innovator drugs to generic alternatives** [9].

Generic **medicine substitution** also plays a crucial role in the **Chinese healthcare system**. The acceptance and **use of generics** are significantly influenced by the **attitudes of healthcare providers**. A **survey** involving **1,644 doctors** and **4,187 pharmacists** found that **most physicians (82.8%, n = 1,362) and pharmacists (89.8%, n = 3,760) correctly defined generic medicines**. Additionally, a similar proportion of doctors (64.1%) and pharmacists (68.2%) agreed that **approved generics are just as effective** as brand-name drugs, while **63.8% of doctors and 69.1% of pharmacists** considered them to be **just as safe**.

Furthermore, **67.6% of doctors** and **71.0% of pharmacists** expressed support for **generic substitution policies**. More than **78% of respondents** indicated that the **prescription of generic medicines in their medical facilities had increased** significantly. However, **lack of confidence** in the **efficacy and safety** of generics, along with **challenges in switching medications for patients**, were identified as key barriers. Despite these concerns, **policies and regulations** aimed at **facilitating the transition to generics** were often viewed as **unnecessary** by some stakeholders [10,11].

A study in the United States found that when only one generic medicine is available on the market, its price is slightly lower than that of the innovator brand. However, when a second generic medicine enters the market, the average price of generics drops to about 50% of the innovator's brand price. With more than five generic medicines available, the price of generics can fall to as low as 20% or even less of the branded drug price. The introduction of a **mandatory generic substitution policy** in **Sweden** led to

a **price reduction** for medicines ranging from 15% to 40%. Similar results were observed in **Finland**, where the average price of some medicines dropped by up to 80%, with a general reduction of **10.6%**.

The impact on drug prices was investigated using a mathematical model that did not account for the effects of **generic drug entry** into the market. This oversight led to an overestimation of the **economic yield** of the new product and the **additional cost-effectiveness ratio (ICER)**. The findings were presented using **acceptable cost-efficiency curves**, which concluded that incorporating generics into **pharmacoeconomic models** leads to more accurate ICER predictions and improved decision-making [12].

As patents expire, public discourse increasingly questions the assumption that the pharmaceutical market will naturally ensure low prices for consumers. The conventional view is that the prices of generic drugs should be low, either decreasing over time or remaining steady. This is true when the **marginal production costs** for a particular generic are low [13].

The presence of multiple generic manufacturers in the **Georgian market** contributes to increased competition, which in turn leads to further price reductions. As different manufacturers offer their versions of the same drug, the increased supply and competition help drive down prices. The **Government of Georgia** has implemented policies and regulations to encourage the use and availability of generics. These measures include granting **market exclusivity periods** to brand-name medicines and allowing generic manufacturers to enter the market after the exclusivity period expires. By developing a **favorable regulatory environment**, the government promotes competition and **price reductions**.

The availability of generics offers consumers a wider range of medication options. This variety allows users to make **informed choices** based on their budgets and preferences, leading to increased access to essential medicines. The use of generics in the Georgian market has the potential to generate significant savings for the healthcare system.

By choosing cost-effective generics, both individual patients and healthcare systems can achieve significant savings, which can then be allocated to other areas of healthcare or used to improve overall healthcare infrastructure.

CONCLUSION

Generic medications, while clinically similar to original brand-name medicines, offer the same quality, efficacy, and safety profiles. However, they are much cheaper. Therefore, by delivering the same therapeutic outcomes, generic medications provide substantial savings for healthcare systems. Public health facilities have long prescribed generic medicines as part of the healthcare sector's cost-saving strategy. This practice should be expanded, and the government should implement more initiatives to encourage the use of generic medications across the country, particularly in private healthcare settings. This approach could help reduce medication costs for the majority of patients who pay for their medications out-of-pocket. Additionally, it is essential to inform both patients and healthcare professionals about the availability of more affordable, bioequivalent medications. By doing so, patients will become more aware of the benefits of generics, reducing their reliance on more expensive brand-name medicines in both public and private healthcare facilities. These initiatives are expected to increase public understanding of generic medicines among Malaysian patients and healthcare professionals, ultimately improving the availability of medicines within the healthcare system as a whole.

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გენერიკული მედიკამენტების გლობალური პოლიტიკის ანალიზი

ნანა შაშიაშვილი
ასოც. პროფესორი; თბილისის სახელმწიფო სამედიცინო უნივერსიტეტი
E-mail: n.shashiashvili@tsmu.edu

ნათია კვიჟინაძე
ასოც.პროფესორი, თბილისის სახელმწიფო სამედიცინო უნივერსიტეტი
E-mail: n.kvizhinadze@tsmu.edu

ნინო ბაქრაძე

ბრემენის უნივერსიტეტი, გერმანია,
E-mail: Bakradzenino12@gmail.com; Ninbak@uni-bremen.de

რეზიუმე

გენერიკულ სამკურნალო საშუალებებზე ხელმისაწვდომობა კრიტიკულ როლს ასრულებს ჯანდაცვის სისტემების ხარჯების შემცირებასა და მოსახლეობისთვის აუცილებელი მედიკამენტებით უზრუნველყოფაში. სტატია მიმოიხილავს გლობალურ პოლიტიკას, რეგულაციებს და მიდგომებს, რომელიც ხელს უწყობს გენერიკების გავრცელებას სხვადასხვა ქვეყნებში, ასევე, მათი მიმოქცევის ბარიერებს, როგორიცაა მარეგულირებელი ჩარჩოს სიმკაცრე, საზოგადოების მხრიდან უარყოფითი შეხედულებები, ბაზრის დინამიკა. საქართველოს მაგალითზე გაანალიზებულია ადგილობრივი რეგულაციები, რომლებიც მიზნად ისახავს კონკურენციის გაზრდას გენერიკული მედიკამენტების გამოყენების წახალისების გზით და მათზე ფასების შემცირებას. ფასის უპირატესობა საშუალებას აძლევს გენერიკებს იყვნენ უფრო კონკურენტული და ხელმისაწვდომი მომხმარებლებისთვის.ჯანდაცვის პროფესიონალების მხარდაჭერა, ინფორმირებულობის ამაღლება და სახელმწიფო რეგულაციების სრულყოფა ხელს უწყობს სამკურნალო საშუალებების რაციონალურ გამოყენებას. აღნიშნულის გათვალისწინებით, ხაზგასმულია ის აუცილებელი ღონისძიებები, რომლებიც გლობალურ და ადგილობრივ დონეზე საჭიროა გენერიკული მედიკამენტების ხელმისაწვდომობის და ჯანდაცვის ხარჯების ოპტიმიზაციისთვის.

საკვანძო სიტყვები: ბიოექვივალენტობა, გენერიკული მედიკამენტები, ჯანდაცვის ხარჯები, მედიკამენტების ხელმისაწვდომობა, ფარმაცევტული ბაზარი.