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Original and generic medicines: clinical, economic and social aspects in the context of health care systems

Lewandowski Marcin[1], Religioni Urszula[2], Barańska Agnieszka[3], Wdowiak Krystian[3], Kobayashi Adam[1], Borowska Mariola[4*], Czech Marcin[5], Wierzbiński Piotr[6], Śliż Daniel[7], Plagens–Rotman Katarzyna[8], Merks Piotr[1]

[1]Department of Pharmacology and Clinical Pharmacology, Faculty of Medicine, Collegium Medicum, Cardinal Stefan Wyszyński University in Warsaw, Poland

[2]School of Public Health, Centre of Postgraduate Medical Education, Warsaw, Poland

[3]Department of Medical Informatics and Statistics with e-Health Lab, Medical University of Lublin

[4]Department of Cancer Epidemiology and Primary Prevention, Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland

[5]Department of Pharmacoeconomics, Institute of Mother and Child, Warsaw, Poland

[6]Polish Society of Holistic Medicine, Warsaw, Poland

[7]3rd Department of Internal Medicine and Cardiology, Medical University of Warsaw, Warsaw, Poland

[8]Center for Pediatric, Adolescent Gynecology and Sexology, Division of Gynecology, Department of Gynecology, Poznan University of Medical Sciences, Poznan, Poland

*Corresponding author: Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland.
Email: mariola.borowska@nio.gov.pl

Abstract: This narrative review synthesizes evidence on clinical, regulatory, economic, and social aspects of generic drug use, focusing on European and Polish contexts. We searched MEDLINE/PubMed, Embase, Scopus, Web of Science, Cochrane Library, and regulatory sources for English and Polish-language records published January 2015 to October 2025. Regulatory authorities apply rigorous bioequivalence and Good Manufacturing Practice standards ensuring generics meet the same quality requirements as branded counterparts. Across most small-molecule indications, these standards predict comparable therapeutic outcomes, with residual caution for narrow-therapeutic-index or modified-release medicines. Despite regulatory assurance, perceptions of inferiority persist among healthcare professionals and patients, influenced by misinformation, inconsistent communication, and branding cues. Economically, generics consistently reduce public and out-of-pocket expenditures and enable reinvestment in innovative therapies. Policy tools such as reference pricing, INN prescribing, and pharmacist substitution shape uptake, though implementation varies. Supply-chain vulnerabilities and market-sustainability pressures threaten continuity of access. Four priority actions emerge: improve transparency of regulatory decisions and product-level information at point of care, standardize professional and public education on generic equivalence, protect sustainable competition through calibrated pricing and diversified sourcing, and prioritize real-world comparative research in sensitive indications. These measures would strengthen trust, ensure reliable access, and allow savings to be reinvested in high-value innovation.

Keywords: Generic medicines, bioequivalence, drug regulation, health economics, patient trust

Introduction

As treatment costs escalate and health inequalities persist, generic drugs have been positioned as a strategic solution to control healthcare expenditures without compromising treatment quality, yet despite their proven equivalence in terms of efficacy and safety, they remain subject to clinical, regulatory, and public controversy. The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the World Health Organization (WHO) provide clear and harmonized definitions of original and generic medicines. An original drug, also known as a reference or branded medicine, is a pharmaceutical product containing a new active substance developed and authorized on the basis of full documentation, including toxicological, pharmacological, and clinical

data [1-4]. The development of an original medicine typically takes 10-15 years and requires substantial investment in research and development.

In contrast, a generic medicine is defined as a drug that contains the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference product has been demonstrated by appropriate bioavailability studies [5]. The primary difference between originators and generics lies in the approval process. While original drugs require the submission of complete preclinical and clinical trial data, generic drugs can refer to existing data of the reference product (Table 1). However, they must undergo rigorous testing to prove bioequivalence, typically through pharmacokinetic studies measuring absorption and plasma concentration [6].

Despite frequent misconceptions, generics are not inferior or simplified versions of original drugs. They are manufactured under the same Good Manufacturing Practice (GMP) standards and are subject to similar post-marketing surveillance requirements [7]. The EMA and FDA impose stringent quality control procedures to ensure batch-to-batch consistency, stability, and safety [8].

This review aims to synthesize current evidence on original and generic medicines across four domains: regulatory frameworks and bioequivalence standards, clinical acceptance and implementation patterns, economic impact and policy mechanisms, and remaining evidence gaps. Particular attention is given to European and Polish healthcare contexts, where policy debates around generic utilization have intensified in recent years.

Methods

We searched MEDLINE/PubMed, Embase, Scopus, Web of Science, and the Cochrane Library for peer-reviewed literature, supplemented by resources from the EMA, FDA, WHO, URPL (Polish Office for Registration of Medicinal Products), Ministry of Health (Poland), National Health Fund (NFZ), OECD, EUR-Lex, and relevant industry reports. The search covered publications from January 1, 2015 to October 14, 2025, in English and Polish languages.

Example keyword searches used in the databases included: "generic drug*" OR "generic medicine*" OR "originator" OR "brand-name" OR "generic substitution" OR INN AND bioequivalence OR regulation OR "European Union" OR EMA OR FDA OR reimbursement OR pricing OR policy OR pharmacovigilance OR acceptance OR "patient trust" AND Poland OR Europe.

We included peer-reviewed primary studies and reviews of generic drugs, official documents/regulations, and reports from public and international institutions. In accordance with the objectives of the article, we used narrative synthesis.

Regulatory framework and bioequivalence

The approval of pharmaceutical products is one of the most heavily regulated processes in modern medicine. Regulatory agencies such as the EMA, the FDA, and national authorities like the Polish Office for Registration of Medicinal Products (URPL) enforce strict requirements to ensure the safety, efficacy, and quality of medicines available to the public.

Original drugs undergo comprehensive development including preclinical studies on pharmacodynamics, pharmacokinetics, and toxicology in laboratory and animal models, followed by three-phase clinical trials demonstrating safety and efficacy in progressively larger populations. Phase I trials assess safety and dosage in healthy volunteers, Phase II trials explore therapeutic efficacy in small patient populations, and Phase III trials compare the investigational drug to existing therapies in larger, often multicenter cohorts. The full dossier submitted to regulatory agencies includes Chemistry, Manufacturing, and Controls (CMC) documentation alongside clinical evidence. The European framework for original drug registration is outlined in Directive 2001/83/EC, whereas in the United States, it is governed by the New Drug Application (NDA) process under the Food, Drug, and Cosmetic Act [9][10].

In Poland, the Pharmaceutical Law (Dz.U. 2001 Nr 126 poz. 1381) regulates the national and centralized procedures for granting marketing authorization. Articles 10 to 20 detail the registration requirements, including the mandatory benefit-risk assessment conducted by the URPL and alignment with EMA decisions for centralized applications [11]. Original drugs receive data exclusivity protection in the EU for a period of 8 years, followed by 2 years of market exclusivity, with an additional year potentially granted for significant new indications, known as the „8+2+1" rule [12].

Table 1. Originator vs. Generic Product - pathway at a glance

Aspect	Originator Product	Generic Product
Evidence for approval	Full preclinical studies + Phase I–III clinical trials; full CMC	Abridged application; must demonstrate bioequivalence
Typical R&D time/cost	~10–15 years; high R&D investment	No full clinical program required
Pharmaceutical equivalence	-	Same active substance(s), strength, pharmaceutical form, and route
Bioequivalence (BE)	-	Pharmacokinetic (PK) studies showing bioequivalence (measure AUC and Cmax)
Quality & safety	Same GMP and post-marketing surveillance for both	Same GMP and post-marketing surveillance for both
Substitution (Poland)	Prescriber may forbid substitution	Pharmacist may substitute with a cheaper equivalent unless prohibited

Generic drugs do not need to replicate the full clinical development of the reference product. Instead, they must demonstrate pharmaceutical equivalence and bioequivalence based on strict regulatory criteria. Pharmaceutical equivalence requires that the generic contains the same active ingredient, is administered in the same dosage form and route, and possesses identical strength. Bioequivalence requires that the pharmacokinetic profile of the generic, especially Cmax (maximum plasma concentration) and AUC (area under the curve), falls within the regulatory acceptance range of 80-125% when compared with the reference product [6][13].

Bioequivalence is typically demonstrated through randomized, crossover clinical studies in healthy volunteers. The EMA and FDA both publish guidance on the design of such studies, including sampling timelines, statistical analysis, and requirements for fasting and fed conditions. In Poland, Article 15 of the Pharmaceutical Law allows for the abridged application, in which the applicant may omit preclinical and clinical trial data by referring to the original product's dossier, provided they can demonstrate equivalence [11]. An essential condition for submission of a generic application is that the reference product must be authorized for at least 8 years, in line with EU law. This safeguards innovation while allowing time-limited market exclusivity before opening the market to competition.

Regulatory agencies use internationally accepted criteria to ensure that generic medicines are therapeutically equivalent to their brand-name counterparts. The FDA requires that the 90% confidence intervals for the ratios of the generic to brand-name drug in both Cmax and AUC fall within the range of 80-125% [14]. Similarly, the EMA follows harmonized European legislation under Directive 2001/83/EC, with corresponding requirements for bioequivalence [9]. These standards are based on robust scientific principles and are recognized globally. WHO's Essential Medicines List routinely includes generic formulations as therapeutically equivalent to branded options, reinforcing their legitimacy in evidence-based practice [15].

From a health systems perspective, generics are a key component of cost containment strategies [16]. They help reduce pharmaceutical expenditures, improve access to essential treatments, and free up resources for innovation and high-cost therapies, such as personalized medicine or orphan drugs. According to the Polish State Drug Policy Report 2018-2022, generics accounted for over 60% of prescription volume and approximately 40% of total drug spending [17]. The report notes that increasing the use of generics is one of the key policy levers to ensure the financial sustainability of the public healthcare system.

From a clinical perspective, the bioequivalence criteria set by regulators are designed to predict therapeutic equivalence [18]. A systematic review by Mondelo-García et al. (2018) confirmed that pharmacokinetic bioequivalence is a reliable surrogate for therapeutic outcomes in most cases [19]. However, physicians and patients continue to express skepticism, particularly regarding narrow therapeutic index drugs (NTIDs), modified-release formulations, or biologics and biosimilars. In Poland, the Regulation of the Minister of Health allows pharmacists to substitute prescribed brand-name drugs with a cheaper equivalent if available, unless the physician explicitly forbids substitution [20]. This legal framework supports cost

containment and increases access but also demands high confidence in the therapeutic equivalence of generics.

Acceptance and implementation

The acceptance of generic medicines by healthcare professionals and patients remains a critical determinant of their effective utilization. Although generics are scientifically proven to be equivalent to their original counterparts, attitudes and behaviors toward these products are influenced by a complex interplay of trust, experience, policy, and communication.

Physicians play a pivotal role in shaping drug utilization trends. Their confidence in the efficacy and safety of generic drugs directly affects prescribing behaviors. Multiple international studies indicate that physicians often hold ambivalent or negative views about generics, particularly in cases involving medications with narrow therapeutic indices, psychotropics, antiepileptics, or cardiovascular agents [18]. A study conducted by Mondelo-García et al. (2018) in Spain revealed that both physicians and pharmacists expressed concerns regarding the therapeutic interchangeability of generics [19]. Despite regulatory assurances, some clinicians believed that slight differences in excipients or release mechanisms could affect clinical outcomes [21]. This was especially relevant for elderly patients or those with complex chronic diseases.

In Hong Kong, Lee et al. (2018) found that although many healthcare professionals accepted generics in principle, only a fraction routinely prescribed them [22]. Factors such as lack of transparency about manufacturers, insufficient continuing education, and concerns about patient acceptance were cited as barriers [23]. In similar fashion, physicians in Poland have voiced skepticism toward generics, particularly those imported from outside the EU or produced by manufacturers with limited brand recognition.

In many countries, prescribing by international nonproprietary name (INN) is encouraged to facilitate generic substitution [24]. However, its adoption varies widely. Some physicians prefer to prescribe by brand name due to habit, familiarity, or pressure from pharmaceutical representatives. Others cite concerns about the practical implications of substitution, such as patient confusion, inconsistent packaging, or variations in pill appearance. The 2018-2022 Polish National Drug Policy emphasized the importance of promoting INN prescribing but acknowledged that physician resistance remains a challenge [17].

Patients' trust in generic medicines is another cornerstone of successful implementation. While cost savings are an incentive, perceived inferiority of generics in terms of effectiveness, safety, and quality continues to influence patient preferences. According to Gebresillassie et al. (2018), patients in Ethiopia viewed generics as less effective and more prone to adverse effects, despite no clinical evidence supporting such claims [25]. Cultural beliefs, low health literacy, and the influence of pharmaceutical branding were key contributors to this perception. Similar findings were observed by Lee et al. (2018) among chronic disease patients in Hong Kong, where many expressed reluctance to accept substitution due to fear of treatment failure [22].

In the Polish context, public attitudes toward generics are mixed. The National Drug Policy report notes that although substitution by pharmacists is legally permitted and commonly practiced, patients often request brand-name products, especially when they associate them with previous treatment success. This behavior is further reinforced by inconsistent communication from prescribers and pharmacists. Patients often conflate price with quality. Generics, being cheaper, are sometimes perceived as less potent or subject to less rigorous production standards [26]. This misconception persists despite identical regulatory oversight and GMP standards.

Pharmacists are central to the real-world implementation of generic policies [21]. In most European countries, they are legally authorized to substitute brand-name drugs with equivalent generics unless the prescribing physician explicitly prohibits it. However, their actual engagement in substitution varies depending on national policies, workload, availability of alternatives, and perceived risk. A qualitative study in Spain revealed that pharmacists experienced ethical dilemmas when patients questioned the substitution [19]. Many felt caught between the legal right to substitute and the clinical responsibility to respect patient preferences.

In Poland, the legal framework supports substitution, and pharmacists are incentivized to offer the cheapest reimbursed equivalent available. Nonetheless, the practice is inconsistently applied. The lack of standard guidelines for patient communication

and the absence of visible quality certificates for generics on packaging contribute to hesitation. When physicians write prescriptions using brand names, patients may feel confused or suspicious when offered a different product. To improve substitution rates, the Polish Ministry of Health has proposed introducing labeling systems for generics and improving access to official product comparison databases [17].

The acceptance of generics is shaped by several interconnected factors that operate at individual, institutional, and systemic levels. Education and training form the foundation, with physicians and pharmacists who have received formal instruction in pharmacoeconomics and regulatory science demonstrating greater willingness to prescribe and recommend generics. Prior experience plays a powerful role, as both negative and positive treatment outcomes significantly influence future prescribing patterns and patient acceptance, sometimes creating attribution biases where unrelated adverse effects are incorrectly linked to generic substitution.

Institutional factors also exert considerable influence. Endorsements from professional societies, ministries of health, or academic bodies lend credibility to generic medicines, while the absence of clear guidance often results in inconsistent practices across settings. Cultural and psychological dimensions further complicate the picture, as branding, visual design, and perceived manufacturer professionalism shape perceptions of safety and efficacy independently of clinical evidence. In Poland and similar contexts, foreign-manufactured generics may face additional skepticism despite equivalent regulatory oversight. Regulatory communication serves as a critical bridge between technical standards and public trust. Transparent information about approval processes, GMP inspections, and pharmacovigilance systems can counteract misinformation, but only when presented in accessible formats and through trusted channels.

Economic impact and policy

The economic implications of using generic medicines are among the most frequently cited arguments for their adoption across healthcare systems. Generic drugs offer a unique opportunity to balance financial sustainability with broad access to pharmacotherapy, especially in publicly funded systems.

Generic substitution is widely recognized as a cost-effective strategy for reducing pharmaceutical expenditures. Since generics do not require the same investment in preclinical and clinical development as originator drugs, their entry into the market is typically accompanied by substantial price reductions [27]. According to the European Commission, generic competition can lead to price reductions of 20-80% depending on therapeutic category and country-specific regulatory conditions.

In Poland, the National Drug Policy Report 2018-2022 estimated that generics accounted for approximately 60% of the volume of reimbursed prescriptions and generated significant budgetary savings [17]. The National Health Fund (NFZ) was able to redirect these funds toward innovative therapies and broader reimbursement schemes. A similar trend is observed in other European countries with well-developed generic markets such as Germany, the UK, and the Netherlands, where the widespread use of generics has helped control the growth of drug expenditures despite aging populations and increasing demand for medications.

From the patient perspective, generics also reduce out-of-pocket spending. In systems with co-payment structures, the price differential between brand-name and generic drugs can substantially affect medication adherence [28]. Studies have shown that when lower-cost alternatives are available and accessible, patients are more likely to continue therapy, especially in chronic disease management. A 2021 analysis of prescription data in France indicated that generic substitution improved adherence to antihypertensive drugs and statins in low-income populations.

The introduction of generic drugs increases competition in pharmaceutical markets by eroding the monopoly held by originator manufacturers. This competitive pressure leads not only to price reductions for generics but often also prompts originator companies to reduce the price of their own products [27]. The dynamic pricing environment created by generics contributes to more transparent and equitable drug pricing. In Poland, the reimbursement system includes a reference price mechanism whereby all therapeutically equivalent drugs are grouped, and the public payer reimburses them up to a set limit [17]. This structure incentivizes manufacturers to price their products competitively and rewards the use of the most cost-efficient options.

However, the effectiveness of this model depends on several conditions: timely entry of generics into

the market, enforcement of price transparency, and avoidance of artificial barriers to competition. While the short-term savings from rapid generic entry are significant, policy must also protect the innovation ecosystem. Delays in registration, patent litigation, or strategic behavior by originators can all hinder the timely introduction of generics. This is why national agencies such as the Polish URPL and international institutions such as the EMA continue to streamline approval procedures and monitor anticompetitive practices.

Health systems deploy diverse policy instruments to promote generic utilization, operating across regulatory, economic, and educational domains [29]. Substitution policies represent the most direct mechanism, granting pharmacists either mandatory or discretionary authority to dispense generic alternatives when clinically equivalent products are prescribed by brand name. Complementing this, prescribing by international nonproprietary name (INN) eliminates brand preference at the point of prescription, though implementation remains voluntary in many jurisdictions. Economic levers include financial incentives that reward physicians or pharmacies for generic prescribing or dispensing, as well as differential reimbursement structures that shift cost burdens toward branded products. These are typically reinforced by public awareness campaigns designed to build patient confidence in therapeutic equivalence and counteract misconceptions about generic quality.

In Poland, pharmacists are legally allowed and encouraged to offer generic alternatives when available. However, prescribing by INN is not mandatory, and many physicians continue to prescribe by brand name, which may limit substitution in practice. The 2018-2022 drug policy report acknowledged this limitation and proposed legislative changes to promote INN prescribing in publicly funded institutions [17]. One of the notable incentives in the Polish context is the use of a „lowest-price" reimbursement model, where pharmacies are obliged to offer the cheapest reimbursed equivalent unless otherwise instructed by the prescriber [17]. This policy aims to contain costs but can create friction when patients are switched between products without adequate explanation or when the lowest-price product is temporarily unavailable.

International evidence supports the effectiveness of combined interventions. Kassandros et al. found that generic uptake is highest in countries that integrate prescribing incentives, pharmacist substitution authority, educational campaigns, and robust regulatory oversight [30]. Isolated measures were less effective and sometimes counterproductive, especially when not accompanied by physician and patient engagement.

Despite their potential, generics face multiple structural barriers. Patent extensions and regulatory exclusivities can delay generic entry [28]. Pricing policies that rely solely on discounting may disincentivize generic manufacturers from entering small or saturated markets. In addition, some generic companies have reported difficulties in maintaining supply due to narrow profit margins and global competition, particularly in active pharmaceutical ingredient (API) sourcing.

In the Polish system, economic constraints are further complicated by the reimbursement procedure, which requires regular updating of price lists and reference groups [17]. Manufacturers that fail to meet pricing thresholds may be excluded from reimbursement, limiting their market share despite regulatory approval. The administrative burden of frequent price negotiations has been cited by stakeholders as a potential deterrent to broader generic participation. An additional issue is the concentration of production in a small number of international suppliers, often located in India or China. While these producers are subject to GMP inspections, disruptions in global supply chains, such as those observed during the COVID-19 pandemic, highlight the vulnerability of national markets reliant on imports. Poland's drug policy report calls for increased diversification and local manufacturing capacity to safeguard drug availability.

Evidence gaps and recommendations

Despite decades of scientific validation and policy support, the use of generic medicines continues to face a range of challenges that limit their full potential in health systems worldwide. These challenges span regulatory, clinical, economic, and social domains.

While generics must meet the same Good Manufacturing Practice (GMP) standards as original medicines, concerns about the quality of production persist among both professionals and the public. These concerns are particularly pronounced for products manufactured in countries perceived as having less robust regulatory oversight. Kassandros et al. showed

that patients in Greece evaluated generic drug safety not only on clinical outcomes but also based on country-of-origin heuristics [30]. Similar findings have been documented in Kazakhstan and parts of Eastern Europe, where locally or regionally manufactured generics were viewed with more skepticism than Western European or American brands, even when approved by the same regulatory agencies.

The Polish drug policy report (2018-2022) identified the need to strengthen regulatory capacity, including the frequency and transparency of GMP inspections [17]. It also called for publicly available registers indicating the bioequivalence status and GMP compliance of each marketed product, including generic formulations. These measures would help rebuild trust in generics by aligning regulatory legitimacy with visible markers of quality assurance.

The spread of health-related misinformation, particularly in digital media, has become a growing challenge for the healthcare sector. Misinformation around generic drugs often includes myths about lower effectiveness, more side effects, or inferior safety standards. These narratives are sometimes reinforced by anecdotal experiences, biased reporting, or even by brand-name drug marketing strategies. Research published in 2022 and 2023 has documented how misinformation about generics spreads on social media platforms and forums, especially in contexts of chronic illness or vulnerable populations [31]. For instance, some patients believe that switching from a brand-name antidepressant to a generic caused treatment failure, despite no pharmacological evidence. Once such beliefs become entrenched, they are difficult to counteract with regulatory explanations alone.

Although generics are approved based on bioequivalence studies, questions remain about their long-term therapeutic equivalence in real-world conditions. Randomized controlled trials comparing generics and originators are rare, largely because they are not required by regulatory authorities and offer little commercial incentive. As a result, long-term data on comparative effectiveness, adherence patterns, and health outcomes across diverse patient populations are limited. A systematic review published in 2020 emphasized the lack of independent, non-industry-sponsored studies on the long-term outcomes of generic substitution [32]. While regulatory agencies maintain that the available evidence is sufficient, some physicians continue to question the appropriateness of substitution in specific clinical contexts, such as epilepsy, psychiatry, or immunosuppressive therapy.

Another enduring barrier to generic uptake is the insufficient integration of pharmacoeconomic and regulatory content into medical and pharmaceutical education. Many physicians complete their training without formal instruction on how generics are approved, what bioequivalence means in practice, or how to communicate effectively about substitution with patients. Recent surveys from Central and Eastern Europe show that even among newly graduated physicians, confusion persists about the differences between generics and originators, especially regarding excipients, dosage forms, and therapeutic equivalence [33]. Pharmacists are typically better informed, but often lack structured tools for patient communication on this topic.

Patients frequently report confusion when their medication is substituted at the pharmacy level, especially when pill appearance or packaging changes. Without clear explanation, such substitutions may erode trust, reduce adherence, and lead to higher healthcare use. Despite legal frameworks supporting substitution, the lack of consistent communication strategies creates uncertainty and contributes to the negative perceptions of generics. Studies from 2021-2023 suggest that when patients are engaged in discussions about cost-effectiveness, therapeutic equivalence, and regulatory oversight, they are more likely to accept and adhere to generic therapies [34].

While generics reduce costs for payers and patients, they often operate on thin profit margins, which can jeopardize long-term supply sustainability. Manufacturers may withdraw from markets where regulatory complexity or pricing policies make generic production financially unviable. In extreme cases, this has led to drug shortages, particularly in smaller or low-income countries. Recent commentary in the pharmacoeconomic literature highlights the importance of balancing price regulation with incentives for sustained participation in the generic market [35]. The COVID-19 pandemic exposed the fragility of global supply chains, prompting calls for greater diversification of active pharmaceutical ingredient (API) sources and even local manufacturing capacities.

Based on this synthesis, four priority actions emerge. First, regulatory evidence must be made visible and usable at the point of care by providing

clear, product-level information on bioequivalence, GMP status, and substitution eligibility, linked to reimbursement lists and dispensing systems. Second, education and communication on generics should be standardized through concise national guidance for prescribers and pharmacists, covering INN prescribing norms, switching in sensitive indications, and consistent, patient-friendly counseling at the point of dispensing. Third, sustainable competition and supply security must be protected by calibrating pricing, reimbursement and procurement to keep multiple manufacturers engaged, diversifying API sources, and operating early-warning and stock-monitoring mechanisms to prevent shortages. Fourth, real-world comparative research should be prioritized where uncertainty is greatest, particularly for narrow-therapeutic-index and modified-release medicines using routine prescribing, dispensing and outcomes data to inform clinical guidance.

Priority research gaps include long-term comparative effectiveness in narrow therapeutic index drugs, implementation science studies of communication interventions at the point of prescribing and dispensing, and health economic analyses that account for both static efficiency gains and dynamic innovation incentives. Publicly funded research programs could address this gap, with comparative effectiveness research involving generics prioritized in national research agendas, especially in therapeutic areas with historically low substitution rates.

Conclusions

Generic medicines have a strategic role in modern healthcare systems, delivering outcomes comparable to originators while improving affordability and access. Their uptake, however, is shaped by perceptions, communication quality, and the effectiveness of policy instruments. In the EU and Poland, stringent requirements for pharmaceutical quality and bioequivalence safeguard safety and efficacy, yet differences in approval pathways, residual clinical caution for complex or narrow-therapeutic-index products, and supply-side vulnerabilities still create practical barriers.

Implementing the recommended measures would strengthen trust, ensure reliable access, and allow savings from generic use to be reinvested in high-value innovation, helping health systems balance affordability with sustained therapeutic progress. Balancing innovation with affordability requires coherent policies that recognize the complementary roles of original and generic medicines in achieving resilient and equitable healthcare systems.

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