JOURNAL OF WORLD SCIENCE
https://jws.rivierapublishing.id/index.php/jws
Volume 5 No. 6 June 2026

P-ISSN: 2828-8726
E-ISSN: 2828-9307

From Lowest Unit Price to Lowest Total Supply Risk: A System Shift Framework for Resilience in the Global Generic Pharmaceutical Industry

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Keyword:
Generic Medicines; Biosimilars; Drug Shortages; Active Pharmaceutical Ingredients; Procurement

Abstract
Generic medicines are routinely framed as a success of price competition, yet recent evidence suggests that the same competitive architecture which lowers unit prices may also weaken supply resilience. Drug shortages, approved-but-unlaunched generics, geographically concentrated active pharmaceutical ingredient (API) production, sterile-injectable vulnerabilities, and the rising technical complexity of biosimilars indicate that the global generic pharmaceutical industry is undergoing a deeper system transition. This article developed a System Shift framework to analyse these structural challenges, linking seven analytical factors: system condition, domain lock, actors, chokepoints, position, strategy, and feedback. Using a public-source qualitative comparative case analysis of twenty companies across global, Indian, European, North American, Chinese, Korean, South African, and Southeast Asian contexts, the paper identifies recurring patterns of vulnerability and strategic adaptation. The analysis shows that generic firms are not a homogeneous low-margin group; they include global off-patent platforms, vertically integrated Indian exporters, sterile-injectable specialists, biosimilar platforms, regional branded-generic leaders, and national manufacturers. Across these archetypes, the dominant feedback signal remains lowest unit price, while quality maturity, supplier redundancy, and launch reliability remain weakly rewarded. The central conclusion is that generic pharmaceutical governance must shift from a cheapest-unit paradigm toward a lowest-total-supply-risk paradigm. Procurement, regulation, and corporate strategy must incorporate multi-award tendering, explicit supply-security criteria, accelerated regulatory variation pathways, resilient API sourcing, and transparent shortage-prevention feedback loops. The paper contributes a conceptual and policy framework for reinterpreting generic medicines as resilience infrastructure rather than merely low-cost therapeutic substitutes.

INTRODUCTION

Generic medicines occupy an unusual position in modern health systems. They are commercially ordinary yet socially indispensable. They are expected to reduce expenditure, expand access, maintain equivalent quality, and remain available even when margins are thin. For decades, the policy story around generics was largely optimistic: patents expire, multiple manufacturers enter, prices fall, and patients gain access. That story remains partly true. It is also incomplete.

A more difficult reality has emerged. Many of the medicines most vulnerable to shortage are old, off-patent, clinically essential, and inexpensive (Nass *et al.* 2018; Vyas *et al.* 2019; Adetunji *et al.* 2024). The problem is especially visible in sterile injectables, hospital products, and other products whose manufacturing complexity is high while market rewards are often low. The U.S. Food and Drug Administration (FDA) identified three root causes of drug shortages: limited incentives to produce less profitable medicines, insufficient market

reward for mature quality systems, and logistical and regulatory challenges to recovering from disruption (U.S. Food and Drug Administration, 2019). IQVIA Institute (2024) further reported that a substantial share of approved generic products had not been launched, demonstrating that regulatory approval does not automatically become real supply.

The upstream structure of generic supply chains intensifies this fragility. Socal et al. (2023) showed that generic API production serving the United States is globally distributed but concentrated across facilities and countries, with many APIs produced by only one or a small number of facilities. A procurement architecture designed primarily around unit-price reduction therefore interacts with a manufacturing architecture that often lacks redundancy. The result is a system that appears efficient under normal conditions but becomes brittle under shock.

This article argues that the global generic pharmaceutical sector is not merely facing a set of operational problems. It is facing a system shift. The old paradigm treats generic medicines primarily as price-reducing substitutes. The emerging paradigm must treat them as resilience infrastructure: products whose value lies not only in affordability but also in continuity, quality, manufacturability, regulatory reliability, and strategic supply security (Mital *et al.* 2014; Anderson 2020; Dada *et al.* 2024; Bilchenko 2025).

To make that argument precise, the article develops and applies a seven-factor System Shift framework: system condition, domain lock, actors, chokepoints, position, strategy, and feedback. The framework is used to analyse twenty generic and biosimilar pharmaceutical companies representing different strategic archetypes. The purpose is not to rank companies or assign fault. It is to understand how shared systemic constraints act differently across positions, and how company strategies respond to those constraints.

The literature on generic medicines has traditionally emphasized market entry, therapeutic equivalence, price competition, and savings to payers. More recent work, however, has highlighted the limits of competition when the relevant market outcome is not merely price but reliable supply. Conti and Wosinska (2025) describe generic drug shortages as a market failure that persists despite competition because price adjustments, entry responses, and quality information are constrained by regulation, contracting, and information asymmetry.

Empirical analyses of shortages reinforce this interpretation. Dave et al. (2018) examined predictors of shortages and the association with generic drug prices, while Tucker et al. (2020) reviewed the shortage literature and described an era in which shortages became persistent rather than exceptional. Tucker and Daskin (2022) modelled pharmaceutical supply chain reliability and showed that reliability cannot be assumed when supply networks are thin, demand is uncertain, and recovery mechanisms are slow.

Policy institutions have moved in a similar direction. The FDA framed shortages as a structural problem of incentives, quality signaling, and recovery barriers. The European Medicines Agency (2024) recommended measures for critical medicines that include increased manufacturing capacity, supplier diversification, stockpiling, shortage prevention plans, and accelerated variation procedures. The European Commission (2025) proposed the Critical Medicines Act to support manufacturing, strengthen supply chains, and incorporate reliable supply into public procurement. These developments mark a shift from a narrow medicine-approval lens to an industrial and health-system resilience lens.

The biosimilar literature adds another layer. Biosimilars extend the logic of post-exclusivity competition into biologic medicines, but they do not reproduce the economics of conventional small-molecule generics. Development costs, analytical burdens, market-access barriers, interchangeability debates, and physician-patient confidence shape uptake. As a result, biosimilar competition is not simply a cheaper version of generic competition; it is a more complex technological and commercial system.

Across these literatures, a common gap remains. The sector is often analyzed either at the policy level, through shortages and procurement, or at the firm level, through strategy and portfolio decisions. What is missing is a framework that links the two. The System Shift approach proposed here fills that gap by reading company strategy as an adaptive response to system condition, domain lock, actors, chokepoints, and feedback loops.

This research aims to develop a seven-factor System Shift framework (system condition, domain lock, actors, chokepoints, position, strategy, and feedback) to diagnose structural vulnerabilities in the global generic pharmaceutical industry, apply it through a qualitative comparative case analysis of twenty companies across diverse geographies, identify recurring patterns of strategic adaptation across six archetypes, analyze how the dominant feedback signal of lowest unit price misaligns with supply resilience, and propose a transition to a lowest-total-supply-risk paradigm. Theoretically, the research reframes generic medicines as resilience infrastructure rather than merely low-cost substitutes and offers a transferable lens for other essential industries. Practically, it provides actionable guidance for policymakers, procurement agencies, and regulators to redesign tendering systems with multi-award frameworks and supply-security criteria, while helping generic companies reposition toward complex generics, biosimilars, and sterile-injectable capabilities, and communicate supply reliability as measurable evidence.

METHOD

This article used a qualitative comparative case analysis based on publicly available sources. The method is appropriate because the research question concerns cross-case patterns, strategic positioning, and system-level interpretation rather than causal estimation from a proprietary dataset. The aim is analytical generalization: to identify how different company archetypes experience the same structural pressures and how those pressures reveal a broader system transition.

Twenty companies were purposively selected to capture variation across geography and business model: Sandoz, Teva, Viatris, Sun Pharmaceutical Industries, Cipla, Dr. Reddy's Laboratories, Aurobindo Pharma, Lupin, Hikma Pharmaceuticals, Fresenius Kabi, Amneal Pharmaceuticals, Apotex, STADA, Krka, Zentiva, Fosun Pharma, Henlius, Celltrion, Aspen Pharmacare, and Dexa Group. The sample includes global generic incumbents, Indian exporters with API integration, sterile-injectable specialists, biosimilar-focused firms, regional European branded-generic platforms, and national or regional manufacturers from emerging health systems.

Sources included peer-reviewed literature, official documents from WHO, FDA, EMA, and the European Commission, IQVIA Institute reports, corporate annual reports, official company pages, SEC filings, and official regulatory disclosures. The search period focused on 2016-2026, with older sentinel documents included when necessary for contextual

interpretation. Searches used combinations of terms including generic medicines, drug shortages, active pharmaceutical ingredient, API concentration, biosimilar market access, sterile injectables, public procurement, tender design, quality systems, and company names.

The analytical procedure had four stages. First, evidence was extracted for each company regarding business model, geographical footprint, product focus, exposure to regulated markets, and strategic direction. Second, each case was coded deductively against the seven System Shift factors. Third, cases were clustered into strategic archetypes. Fourth, cross-case patterns were interpreted to identify system-level policy and corporate implications.

The study has limitations. It relies on public sources and therefore cannot observe confidential supplier contracts, SKU-level margin data, site-level capacity buffers, tender prices, or proprietary demand forecasts. Several company disclosures are self-descriptive and may emphasize strengths more than vulnerabilities. The paper therefore treats company material as positional evidence, triangulated against regulator, policy, and peer-reviewed sources. The purpose is not forensic firm evaluation but systemic interpretation.

Case Selection and Company Archetypes

Table 1. Case-study companies and representative strategic positions

Company	Country/region	Representative position
Sandoz	Switzerland/Europe	Global generics and biosimilars leader
Teva	Israel/global	Global generic incumbent and high-value generics pivot
Viatris	United States/global	Diversified off-patent medicines platform
Sun Pharma	India/global	Specialty-generic global player
Cipla	India/global	Respiratory and complex-generics challenger
Dr. Reddy's	India/global	Integrated generics-API-biosimilar player
Aurobindo	India/global	High-volume vertically integrated generic exporter
Lupin	India/global	Complex generics, inhalation, and injectables specialist
Hikma	United Kingdom/Jordan/global	Regional leader and generic-injectables specialist
Fresenius Kabi	Germany/global	Hospital injectables, IV fluids, and biosimilars specialist
Amneal	United States/global	U.S.-centred complex generics and biosimilars challenger
Apotex	Canada/global	Canadian generic leader with global reach
STADA	Germany/Europe	Hybrid generics, consumer health, and specialty platform
Krka	Slovenia/Europe	Vertically integrated branded-generics regional leader
Zentiva	Czech Republic/Europe	Pan-European affordable-medicines platform
Fosun Pharma	China/global	Integrated mature-products and innovation platform

Company	Country/region	Representative position
Henlius	China/global	Biosimilar and biologics specialist
Celltrion	South Korea/global	Large-scale biosimilar pioneer
Aspen Pharmacare	South Africa/global	Sterile focus brands and regional hospital-market leader
Dexa Group	Indonesia/ASEAN	National manufacturer and regional exporter

Source: Compiled by authors from company annual reports, SEC filings, official corporate websites, and regulatory disclosures (2016–2026)

The companies can be grouped into six broad archetypes. The first is the global off-patent platform represented by Sandoz, Teva, and Viatris. These companies combine scale, regulatory experience, broad portfolios, and exposure to intense price pressure. The second is the integrated Indian exporter, represented by Sun Pharma, Cipla, Dr. Reddy's, Aurobindo, and Lupin. This group combines manufacturing scale with increasing movement into complex generics, specialty products, injectables, and biosimilars. The third is the acute-care and injectable specialist, represented by Hikma, Fresenius Kabi, and Aspen. The fourth is the biosimilar platform, represented by Henlius and Celltrion, with Sandoz, Fresenius Kabi, STADA, and others also participating in the category. The fifth is the regional European platform, represented by STADA, Krka, and Zentiva. The sixth is the national or regional manufacturer in an emerging health system, represented here by Dexa Group.

RESULTS AND DISCUSSION

System condition: affordability without automatic resilience

The first cross-case finding is that generic companies operate in a structural condition that separates affordability from resilience. The market rewards low prices directly and visibly. It rewards continuity, redundancy, and quality maturity only indirectly, and often after failure has occurred. This is the core asymmetry of the generic sector.

The effect differs by archetype. Global platforms absorb price pressure through scale, portfolio breadth, and entry into biosimilars or complex generics. Indian exporters use integration and manufacturing efficiency to compete in regulated markets. Sterile-injectable specialists face higher fixed costs and therefore experience shortage and capacity feedback more immediately. Regional firms rely on trust, branded generics, and market proximity. National manufacturers, such as those in Southeast Asia or Africa, face the additional challenge of building local capacity while depending on globally traded inputs.

The system condition is therefore not simply price competition. It is a mismatch between the public function of generics and the private signals sent to producers. Society needs reliable, high-quality, geographically diversified, continuously available medicines. Yet many procurement systems still select primarily on unit price. A medicine can be cheap and unavailable. That is the paradox.

Domain lock: the persistence of lowest-price logic

Domain lock appears most strongly in procurement design. Tender systems, reference pricing, reimbursement ceilings, and buyer concentration often push the market toward lowest price rather than resilient supply. In normal periods, this appears fiscally efficient. Over time,

however, it can reduce the number of active suppliers, discourage capacity buffers, and push companies away from low-margin essential products.

A second domain lock is regulatory fragmentation. Companies that operate across jurisdictions must manage different dossier expectations, variation procedures, labelling requirements, pharmacovigilance obligations, and inspection histories. These differences are justified by sovereign regulatory responsibility, but they increase the cost and time required to add sites, change suppliers, or recover from disruption.

A third domain lock is technological. Sterile injectables, inhalers, complex depot formulations, liposomal products, transdermal systems, and biosimilars cannot be moved between sites or suppliers as easily as simple oral solids. Technical lock-in makes redundancy expensive. If procurement does not pay for redundancy, the system underinvests in it.

Actors: a multi-actor system with misaligned incentives

The sector is shaped by a dense constellation of actors: regulators, payers, procurement bodies, group purchasing organizations, wholesalers, hospitals, pharmacists, prescribers, patients, API suppliers, contract manufacturers, and corporate partners. Each actor behaves rationally within its mandate, but the aggregate result may still be fragile.

Regulators emphasize safety, efficacy, and quality. Payers and procurement bodies emphasize affordability and budget control. Hospitals emphasize uninterrupted availability. Patients need continuity and confidence. Manufacturers require sufficient economic return to maintain sites, staff, validation systems, and working capital. API suppliers respond to global demand, environmental rules, energy costs, and geopolitical conditions. No single actor alone creates the problem. The vulnerability is produced by the interaction of their incentives.

The policy challenge is therefore not to ask one actor to solve the shortage problem. It is to redesign the feedback between actors. Procurement must recognize quality and continuity; regulators must enable fast but safe site and supplier changes for critical medicines; manufacturers must disclose risk-relevant information; and health systems must translate shortage signals into early interventions rather than delayed crisis management.

Chokepoints: where the system narrows

Across the cases, the most recurrent chokepoints are upstream sourcing, sterile manufacturing capacity, regulatory variation speed, market launch economics, biosimilar market access, and information opacity. API concentration is especially important because finished-dose manufacturers may have multiple registrations but few feasible upstream sources. The fragility is hidden until a site fails, a precursor becomes unavailable, or a price shock propagates through the chain.

Sterile manufacturing is another major chokepoint. Injectable products require aseptic controls, specialized equipment, environmental monitoring, validated processes, and experienced personnel. Capacity cannot be expanded instantly. This explains why shortages in sterile injectables can last longer and cause more acute clinical disruption.

Approved-but-unlaunched generics reveal a commercial chokepoint. If a generic product receives regulatory approval but is not launched, the barrier is not scientific approval but market viability, contracting, supply readiness, litigation risk, or portfolio prioritization. The distinction matters because a policy that counts approvals alone may overestimate real competition and real availability.

Position: strategic heterogeneity among generic companies

The comparative cases show that generic firms occupy different positions in the system. Sandoz and Teva operate with global scale but also face global exposure to price erosion and regulatory complexity. Viatris represents a diversified off-patent model, combining generics with established brands and broader access infrastructure. Indian firms such as Sun Pharma, Cipla, Dr. Reddy's, Aurobindo, and Lupin illustrate the power and burden of manufacturing scale, API integration, and entry into high-barrier products.

Hikma, Fresenius Kabi, and Aspen illustrate how hospital and sterile-injectable positions bring higher clinical relevance and higher fixed costs. Celltrion and Henlius illustrate the biosimilar frontier, where manufacturing science, analytical comparability, market access, and physician confidence become central. STADA, Krka, and Zentiva illustrate regional positioning based on proximity, brand trust, and diversified portfolios. Dexa Group illustrates the national and regional manufacturer facing global supply-chain pressures in a developing-country context.

Position matters because the same system pressure has different implications. Price erosion may push one company toward complex generics, another toward biosimilars, another toward regional branding, and another toward public-private partnership. A policy that treats all generic firms as interchangeable suppliers misses this strategic heterogeneity.

Strategy: moving from volume to resilience and complexity

The dominant strategic response is not merely cost-cutting. It is repositioning. Firms seek higher-barrier products, stronger quality reputations, deeper supply-chain control, broader geographic portfolios, and partnerships that spread commercial or regulatory risk.

One pathway is technological upgrading: complex generics, respiratory devices, injectables, and biosimilars. This pathway can improve margins and reduce direct commodity competition, but it also requires deeper scientific, regulatory, and manufacturing capabilities. Another pathway is vertical integration, especially in API production. Integration can improve control but does not eliminate global dependence on precursors, utilities, logistics, and regulatory approvals. A third pathway is regionalization: building production, distribution, or partnership structures close to target health systems.

The most strategically advanced firms will likely combine these pathways. They will treat supply resilience as an enterprise capability rather than a compliance afterthought. They will map critical SKUs, identify single points of failure, qualify secondary suppliers, track recovery time, and engage procurement agencies with evidence rather than general claims.

Feedback: the wrong signal arrives too late

The most important System Shift finding is that the feedback loop remains miscalibrated. Price reductions are immediate and measurable. Shortage costs are diffuse, delayed, and often borne by patients, hospitals, clinicians, and public agencies rather than by the procurement contract that generated the fragility. This is why the system can appear efficient until it fails.

A better feedback architecture would include routine metrics for supplier concentration, number of qualified sites, days of supply, fill rate, launch delay, regulatory variation time, and quality maturity. These metrics should not replace price; they should sit beside price. The aim is not to make generics expensive. It is to distinguish efficient affordability from brittle cheapness.

In this sense, the feedback shift is the heart of the transition. Once procurement, reimbursement, regulation, and corporate dashboards begin to measure total supply risk, companies receive a different signal. Redundancy becomes investable. Quality maturity becomes visible. Launch reliability becomes valuable. Shortage prevention becomes a routine management function rather than a crisis response.

Cross-Case Synthesis

Table 2. Cross-case archetypes in the global generic pharmaceutical industry

Archetype	**Illustrative cases**	**Dominant chokepoints**	**Typical strategic response**
Global off-patent platforms	Sandoz, Teva, Viatris	Price erosion; buyer concentration; global regulatory complexity	Portfolio optimization; biosimilar expansion; high-value generics; global partnerships
Integrated Indian exporters	Sun Pharma, Cipla, Dr. Reddy's, Aurobindo, Lupin	Regulated-market compliance; commodity price pressure; API and site exposure	Vertical integration; complex generics; specialty products; inhalation and injectables
Acute-care and injectable specialists	Hikma, Fresenius Kabi, Aspen	Sterile capacity; hospital demand shocks; high fixed costs	Capacity investment; product availability transparency; hospital-market specialization
Biosimilar platforms	Celltrion, Henlius, plus biosimilar units of Sandoz, STADA, Fresenius Kabi	Patent and market-access barriers; analytical and commercial complexity	Licensing partnerships; direct commercialization; manufacturing scale and comparability capabilities
Regional branded-generic platforms	STADA, Krka, Zentiva	Payer pressure; need for trust and differentiation; regional supply obligations	Branded generics; consumer health diversification; local networks and portfolio breadth
National/regional manufacturers	Dexa Group and analogous firms in emerging systems	Domestic price ceilings; import dependence; scale disadvantage	Certification, regional partnerships, domestic resilience, and selected export expansion

Source: Authors' synthesis based on qualitative comparative case analysis of twenty companies

The synthesis reveals two important patterns. First, company strategy is increasingly organized around high-barrier capabilities rather than pure volume. Second, health-system resilience depends on the interaction between firm capabilities and policy design. A company may be willing to invest in redundancy, but if procurement treats redundancy as invisible, that investment becomes commercially irrational. Conversely, policy may demand reliable supply, but without capable suppliers and viable margins it remains aspirational.

This explains why a pure market-entry approach is insufficient. More approvals can help, but approvals do not guarantee launch, production continuity, or geographically diversified supply. Similarly, reshoring can help in selected products, but domestic production

without economic sustainability and upstream redundancy may simply relocate fragility. The relevant unit of analysis is not the individual factory or individual product alone. It is the product-supply system.

Policy Implications

The first policy implication is that procurement for critical generics should move from lowest-price winner-takes-all tendering toward multi-award, multi-criteria frameworks. Price should remain important, but it should be weighted alongside supplier redundancy, quality maturity, manufacturing geography, service levels, shortage history, and availability commitments. This is especially important for sterile injectables, antibiotics, oncology medicines, intensive-care medicines, and other clinically essential products.

The second implication is that regulators should create accelerated and predictable variation pathways for critical medicines. Adding a qualified API supplier or alternative manufacturing site can strengthen resilience, but if variation timelines are uncertain, companies may hesitate. Regulatory reliance, work-sharing, and risk-based acceleration can reduce this friction without weakening quality standards.

The third implication is that governments should define critical medicine portfolios and monitor them with supply-risk dashboards. These dashboards should include the number of active suppliers, number of qualified API sources, days-of-supply buffer, order fill rate, shortage history, and time to recovery after disruption. Such metrics would allow policymakers to act before shortage becomes clinically visible.

The fourth implication is that public policy should distinguish between affordable pricing and unsustainable underpricing. A price that is too high limits access; a price that is too low can destroy the supply base. The policy goal is not higher prices as such, but economically viable reliability. That balance requires evidence, transparency, and differentiated treatment of critical products.

Managerial Implications for Generic Companies

For companies, the central managerial implication is that resilience must become a measurable strategic capability. It is not enough to maintain compliance. Firms should map product criticality, supply concentration, site dependency, launch viability, and recovery time. Critical SKUs should be managed with a different risk logic from commodity SKUs.

Portfolio strategy should also shift. Companies that remain trapped in undifferentiated low-margin oral solids may face increasing vulnerability unless they have exceptional scale, integration, or local advantage. Movement into complex generics, injectables, biosimilars, and trusted regional platforms can improve strategic position, but only if accompanied by quality-system maturity and disciplined capital allocation.

Finally, companies should communicate supply reliability as evidence, not rhetoric. Procurement agencies and regulators need data: dual sourcing, validated alternative sites, historical fill rates, deviation management, shortage-prevention plans, and risk mitigation processes. In the future, trusted access may become a more valuable identity than lowest cost alone.

Proposed Metrics for a Lowest-Total-Supply-Risk Regime

Table 3. Proposed metrics for shifting from lowest unit price to lowest total supply risk.

Level	Metric	Policy or managerial purpose
Procurement	Share of critical medicine tenders awarded to more than one supplier	Reduce single-winner exposure for critical products
Procurement	Non-price weighting in tender score	Make reliability and quality visible in award criteria
Regulation	Median approval time for critical site or supplier variation	Shorten recovery and redundancy-building time
Supply chain	Number of qualified API suppliers per critical product	Identify and reduce single-source risk
Manufacturing	Share of critical SKUs with dual-site qualification	Increase recovery options after disruption
Availability	Fill rate or on-time-in-full performance for critical products	Measure real supply reliability
Market access	Share of approved generics unlaunched after 24 months	Detect approval-to-supply failure
Quality	Critical observations, warning letters, and recurring deviations per site-year	Monitor quality maturity and operational risk

Source: Authors' proposal based on framework analysis and policy literature review

Theoretical Contribution

The article contributes to pharmaceutical policy and systems innovation in three ways. First, it reframes generic medicines as resilience infrastructure. This differs from the common view of generics as low-cost substitutes. The substitution function remains important, but the resilience function is increasingly decisive.

Second, it integrates firm strategy and health-policy design. The same company decision can be interpreted differently depending on the system feedback around it. A decision to exit a low-margin product may appear commercially rational at the firm level and clinically dangerous at the system level. The System Shift framework makes that tension visible without reducing it to blame.

Third, it provides a transferable framework for other essential industries where low price, quality, continuity, and public dependence interact. The seven factors can be applied to medical devices, diagnostics, vaccines, food systems, energy, or digital infrastructure when the central problem is the transition from cost minimization to resilience.

Limitations and Future Research

This study is conceptual and comparative, not econometric. It does not estimate causal effects of tender design, price levels, or company strategy on shortage outcomes. Its contribution lies in system interpretation and framework development.

Future research should test the framework using product-level datasets that combine price, supplier count, API origin, launch status, shortage duration, and regulatory observations. A second research direction is comparative policy analysis of procurement models that reward supply security. A third is company-level analysis of how quality maturity and supply-chain redundancy affect launch reliability and shortage prevention.

The paper also depends on public disclosures, which are uneven across companies and countries. Some variables central to resilience, such as days-of-supply buffers and supplier concentration by SKU, are rarely public. Greater transparency would improve both academic research and policy design.

CONCLUSION

The global generic pharmaceutical industry is entering a new phase. The old policy promise of generics - lower prices through competition - remains essential, but it is no longer sufficient. Health systems now need generic medicines that are affordable, continuously available, geographically resilient, technically reliable, and trusted by clinicians and patients. The System Shift framework shows why the transition is difficult. The system condition rewards low price more directly than resilience. Domain locks in procurement, regulation, and technology slow adjustment. Actors have rational but misaligned incentives. Chokepoints concentrate risk in API sourcing, sterile capacity, regulatory variation, launch economics, and biosimilar market access. Company positions differ, strategies are uneven, and feedback often arrives too late in the form of shortages. The central shift required is therefore from lowest unit price to lowest total supply risk. This does not abandon affordability. It protects it. A generic medicine that disappears from the market is not affordable in any meaningful sense. The next generation of generic pharmaceutical policy must recognize reliable supply as part of access, quality as part of value, and resilience as part of justice in health systems.

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