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Risk Management Strategies in Global Supply Chains of Active Pharmaceutical Ingredients

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ABSTRACT

The article examines risk management strategies in global supply chains of active pharmaceutical ingredients (APIs), which underpin the availability and affordability of generic and branded medicines. The study addresses the growing instability in API sourcing caused by the geographical concentration of production, geopolitical tensions, regulatory heterogeneity, and recurrent quality failures. The research objective is to systematise vulnerabilities in API supply chains and to evaluate managerial and policy tools that strengthen resilience without undermining cost efficiency. The work relies on a structured review of recent empirical and analytical studies on pharmaceutical supply chains, complemented by a comparative analysis of regulatory and industrial initiatives. Special attention is paid to risk assessment frameworks, resilience and criticality metrics, and strategic options such as diversification, reshoring, strategic stockpiling, and collaborative governance. The conclusions highlight combinations of operational and institutional measures that reduce the probability and impact of disruptions. The article is intended for scholars and practitioners in pharmaceutical management, health economics, supply chain governance, and quality systems, as well as regulators designing interventions for strategically significant medicines.

Keywords: active pharmaceutical ingredients, pharmaceutical supply chains, risk management, supply chain resilience, global sourcing, drug shortages, quality risk, geopolitical risk, diversification, reshoring

INTRODUCTION

Active pharmaceutical ingredients form the core of modern pharmacotherapy and define both therapeutic efficacy and cost structure of finished dosage forms. Over recent decades, API production has migrated to a limited group of countries with pronounced cost advantages, while finished drug manufacturing for major markets has remained more geographically diversified. Such fragmentation of value creation between upstream and downstream stages increased exposure to geopolitical shocks, export restrictions, industrial accidents, and regulatory failures in distant jurisdictions.

Recent years have shown that interruptions in API supply rapidly translate into medicine shortages, price spikes, forced therapeutic substitutions, and, in some therapeutic areas, deterioration of clinical outcomes. Governments and multilateral organisations respond with industrial policy initiatives, regulatory reforms, and monitoring systems; yet pharmaceutical firms still face intense pressure to minimise procurement costs and inventory levels. This tension between efficiency-driven globalisation and the need for resilience defines the management problem studied in the article.

The study aims to systematise risk management strategies for global API supply chains and assess their effectiveness from the perspectives of supply continuity, quality assurance, and the long-term sustainability of pharmaceutical markets.

The research objectives are formulated as three interrelated tasks:

1. To synthesise current knowledge on structural vulnerabilities in global API supply chains, including geographic concentration, ownership patterns, quality incidents, and regulatory dependencies.
2. To summarise existing conceptual and quantitative frameworks for risk identification, assessment, and measurement of resilience, criticality, and vulnerability in pharmaceutical and medical product supply chains.
3. To classify and critically examine risk mitigation strategies applied at the firm, network, and policy levels, with emphasis on their applicability to APIs and their integration into economic decision-making in pharmaceutical companies.

Scientific novelty lies in the targeted focus on API supply chains rather than pharmaceutical supply chains in general, in linking health outcomes and industrial structure through the concept of supply chain criticality, and in integrating insights from operations research, health policy, and emerging market studies into a consolidated analytical framework tailored to APIs.

MATERIALS AND METHODOLOGY

The study relies on secondary data and analytical materials from recent scientific publications and policy reports devoted to pharmaceutical and API supply chains. The literature base was purposefully restricted to the last five years to capture post-COVID structural shifts and current debates on reshoring and resilience.

S. Adak [1] examines empirical vulnerabilities of API supply chains under disruptions and proposes resilience-oriented managerial responses, focusing on the concentration of production and limited transparency of upstream tiers. W. D. BenAmor, Á. Labella, H. M. Frikha, and L. M. Martínez [2] develop a quantitative risk assessment model for pharmaceutical supply chains during the COVID-19 epidemic, applying multi-criteria methods to logistics outsourcing decisions and demonstrating how composite risk scores guide mitigation strategies. C. Ciceri, C. Borsani, M. Guida, M. Farinelli, and F. Caniato [3] analyse impact pathways in pharmaceutical supply chains from a multi-actor standpoint, mapping how operational, regulatory, and geopolitical risks propagate across the network. A. Goswami, A. Baveja, X. Ding, B. Melame, and F. Roberts [4] propose an integrated framework for modelling pharmaceutical supply chains with explicit representation of disruptions and pre- and post-disruption mitigation levers. M. Kashif [5] studies risk management practices in the pharmaceutical industry of a large emerging market, revealing gaps between conceptual approaches and actual implementation in firms. V. F. Keeton [6] conceptualises pharmaceutical supply chains as a structural determinant of health for children with ADHD, linking supply reliability of specific medicines to access and health equity. R. Machta and co-authors [7] prepare a comprehensive report on defining and measuring resilience, criticality and vulnerability in medical product supply chains, offering operational metrics and indicators for policy use. D. J. Postma, P. A. G. M. De Smet, A. K. Mantel-Teeuwisse, H. G. M. Leufkens and K. Notenboom [8] conduct a cohort study of upstream supply chains for ten high-use medicines, quantifying geographic distribution and interdependencies between API and finished product manufacturers.M. P. Socal, K. Ahn, J. A. Greene and G. F. Anderson [9] analyse competition and vulnerabilities in the global supply chain for US generic APIs, documenting concentration patterns and exposure of shortage-prone products. Finally, B. Takawira and E. Mutambara [10] develop a strategic framework for pharmaceutical supply chains in emerging markets under pandemic disruptions, emphasizing local production, collaborative disruption management, and digitalization.

The article uses a structured narrative review with purposive selection of sources specialising in API and pharmaceutical supply chain risk, supplemented by elements of systematic review for the identification of core conceptual frameworks. Comparative analysis

is applied to juxtapose empirical evidence across countries and therapeutic areas, and to contrast firm-level strategies with policy-level interventions. Conceptual synthesis is used to integrate taxonomies of risks, resilience metrics, and mitigation instruments into a coherent scheme for API supply chains. Qualitative content analysis of the selected publications supports the derivation of typical strategic responses and their conditions of effectiveness.

RESULTS AND DISCUSSION

The reviewed literature reflects a shift from a generic discussion of disruption towards a detailed examination of vulnerabilities specific to APIs and upstream pharmaceutical activities. S. Adak [1] shows that API supply chains often rely on a small number of intermediate suppliers and manufacturing facilities, combined with long, opaque tiers between raw materials and finished dosage forms. The study highlights recurring patterns: geographical clustering of key intermediates in a limited set of regions, insufficient diversification of suppliers for critical molecules, and dependency on intermediaries for regulatory documentation and quality evidence. These features amplify the impact of local shocks—such as plant shutdowns, export controls, or quality non-compliance—on global medicine availability.

Quantitative evidence from D. J. Postma et al. [8] confirms the magnitude of concentration for high-use medicines. For 407 authorised products covering ten widely prescribed substances in the Netherlands, 50 of the 90 API manufacturing sites were located in Asia, and only 38 were in Europe; for half of the substances, a majority of the API sites were outside Europe. The cohort design enables the mapping of interdependencies between marketing authorization holders, API producers, and finished product manufacturers, revealing that several marketing authorization holders rely on identical upstream facilities. The concentration of API production for multi-source products reduces the apparent redundancy created by the number of branded and generic versions on national markets.

M. P. Socal et al. [9] obtain similar results for the US generic market. Using the Cortellis Generics Intelligence database, the authors identify 565 facilities that produce 1,379 generic APIs across 42 countries. However, they also show that for shortage-prone molecules, the effective number of independent API producers is often minimal. The paper links these structural conditions with recurrent shortages and argues that intense price competition in off-patent markets encourages consolidation of upstream manufacturing into the lowest-cost jurisdictions.

Keeton's work [6] adds a health-equity perspective by demonstrating how such structural dependence on distant API suppliers influences access to stimulant medications for children with ADHD. The analysis examines how production interruptions or regulatory actions affecting individual API manufacturers lead to stockouts, forced therapeutic switching, and treatment discontinuation, particularly among publicly insured and low-income populations. This link between supply chain architecture and distribution of health outcomes justifies treating API supply security as an element of health policy rather than a purely commercial issue.

Risk assessment studies provide instruments to quantify exposure and guide prioritisation of mitigation measures. W. D. BenAmor et al. [2] propose a multi-criteria evaluation of risks associated with logistics outsourcing in pharmaceutical supply chains during the COVID-19 epidemic. Using fuzzy Analytic Hierarchy Process and PROMETHEE methods, the authors combine criteria such as supplier reliability, lead-time variability, information quality, and geopolitical stability into composite risk scores that rank outsourcing options. The approach illustrates how quantitative risk modelling supports decisions on whether to centralise logistics with a single provider or maintain more fragmented but diversified arrangements.

At a broader supply-chain level, the framework by A. Goswami et al. [4] provides a structured approach for mapping disruptions and countermeasures. The authors construct a two-step process: first, a detailed supply chain map from the perspective of a focal firm; second, overlaying this map with classes of disruptions—natural hazards, cyberattacks, regulatory changes, quality incidents, geopolitical events—identified from historical data and expert opinion. The model distinguishes pre-disruption measures (such as dual sourcing, safety stocks, nearshoring, and supplier audits) from post-disruption responses (such as emergency reallocation of orders, regulatory flexibilities, and temporary therapeutic substitutions), and evaluates their expected impact on service levels and costs.

Qualitative studies enrich the picture by capturing perceptions and coordination problems among actors. The multi-actor study by C. Ciceri et al. [3] investigates how pharmaceutical manufacturers, distributors, hospitals, regulators, and technology providers perceive risks and responsibilities. The results indicate that upstream actors emphasise regulatory and cost pressures, while downstream actors focus on demand uncertainty and information deficiencies, leading to misaligned incentives for investment in resilience. The study highlights the importance of governance mechanisms that allocate the cost of redundancy and ensure transparency across the network, rather than placing the burden solely on individual firms.

Evidence from emerging markets illustrates additional vulnerability channels. M. Kashif [5] analyses risk management practices in the pharmaceutical industry of Pakistan and finds that formal risk registers, scenario planning, and quantitative assessment are rarely embedded into routine operations. The study highlights reliance on reactive crisis management, limited data integration across functions, and dependence on a few international suppliers of APIs, all of which magnify the impact of currency volatility and trade restrictions. B. Takawira and E. Mutambara [10] focus on South African supply chains during the pandemic and show that firms responding more successfully combined local API or formulation initiatives, long-term contracts with key suppliers, and collaborative planning with regulators and healthcare providers.

The policy-oriented report by R. Machta et al. [7] provides a vocabulary and metrics for assessing the resilience, criticality, and vulnerability of medical product supply chains. Criticality links clinical importance and the lack of therapeutic substitutes. Resilience characterises a supply chain's ability to absorb and recover from shocks, while vulnerability denotes exposure to disruptions arising from geographic concentration, complexity, and lack of transparency. The report proposes indicators such as the number and diversity of manufacturing sites, geographic Herfindahl indices, dependence on single-source intermediates, and time to recover. These metrics can be adapted specifically to APIs and combined with shortage data to prioritise interventions.

Bringing together these empirical and conceptual contributions enables visualisation of typical concentration patterns and associated risks for APIs. Figure 1 illustrates, using data from D. J. Postma et al. [8], how API manufacturing sites for ten high-use pharmaceuticals are distributed between Asia and Europe, and how many finished product manufacturers depend on each API site.

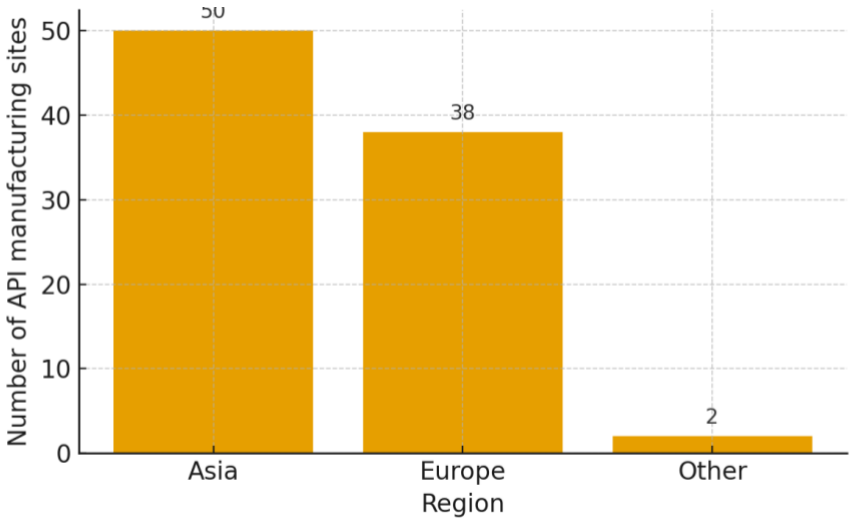

Figure 1. Geographic distribution of API manufacturing sites for ten high-use medicines and corresponding dependencies of Dutch marketing authorisation holders (compiled by author based on [8])

The figure shows that more than half of the upstream sites are located in Asia, while European sites account for the majority of the remainder, with negligible capacity elsewhere. Many Dutch marketing authorisation holders share the same upstream facilities, so that a disruption at a single Asian plant can influence several nominally independent finished-product suppliers. In combination with Socal et al.'s global mapping [9], this evidence suggests that risk management strategies that focus solely on the number of registered products or finished dosage manufacturers underestimate the actual supply concentration.

In terms of concrete risk management strategies, the literature converges on several recurring approaches. First, the geographic diversification of API suppliers and dual sourcing for critical molecules have been repeatedly identified as effective, but are constrained by regulatory requirements, the costs of qualifying new sites, and the limited availability of viable alternative manufacturers [1, 2, 8, 9]. Second, strategic stockpiling and safety stocks for high-criticality APIs can buffer short-term disruptions, though they require financing and careful rotation to mitigate obsolescence [4, 7, 10]. Third, information-sharing platforms and digital tools improve visibility across tiers, enabling earlier detection of emerging disruptions and more coordinated responses [3, 7, 10]. Finally, industrial and trade policies, such as incentives for domestic or regional API production for essential medicines, are proposed as complements to firm-level measures, particularly for highly critical products with low commercial margins [6, 7, 9, 10].

These findings indicate that risk management for global API supply chains cannot rely on a single instrument. Effective strategies combine internal measures—such as procurement diversification, inventory policies, and quality oversight—with external coordination through contracts, industry collaborations, and public-sector programs that recognise the public-good character of supply resilience.

The reviewed evidence indicates that vulnerabilities in API supply chains originate from structural economic forces and regulatory choices, rather than isolated managerial errors. Cost-driven globalisation produced highly efficient but fragile upstream structures dominated by a small number of regions and manufacturers [1, 8, 9]. At the same time, downstream competition and procurement rules in many health systems favour the lowest unit prices, leaving little space for firms to internalise the cost of redundancy. Keeton's analysis [6] demonstrates how such arrangements translate into unequal health outcomes when supply failures disproportionately affect medicines used predominantly by vulnerable groups.

Table 1 summarises the principal categories of risk for global API supply chains, as described in the selected studies, and illustrates how they materialise in practice.

Table 1: Main categories of risk in global API supply chains and empirical manifestations [1–10]

Risk category	Description in relation to APIs	Empirical manifestations
Geographic concentration	Predominance of API and key intermediate manufacturing in a limited set of countries and even single industrial clusters	The majority of API sites for high-use medicines are located in Asia; very few facilities supply several generic APIs for the US market
Supply chain opacity	Limited visibility beyond direct suppliers, complex ownership structures, and reliance on brokers	Marketing authorisation holders sharing upstream facilities without full awareness; difficulties in tracing the origin of quality incidents
Quality and regulatory risk	Heterogeneous enforcement of GMP, inspection capacity, and data integrity requirements across jurisdictions	Recurrent import alerts, forced shutdowns of API plants, withdrawal of marketing authorisations
Logistical and operational disruption	Transport bottlenecks, port closures, pandemic-related restrictions, and energy price spikes	Extended lead times for APIs, a sudden lack of shipping capacity, and increased cost of air freight during crises
Demand and policy shocks	Abrupt shifts in demand due to epidemics, guideline changes, reimbursement decisions, export bans, and trade disputes	Surges in demand for selected APIs; restrictions on exports from major supplying countries; rapid exhaustion of safety stocks
Governance and coordination gaps	Misalignment of incentives and responsibilities among firms, regulators, and payers	Under-investment in redundant capacity and transparency tools; limited data-sharing on shortages and capacities

The table illustrates that risks are interdependent: geographic concentration interacts with regulatory risk, while governance gaps exacerbate the impact of operational disruptions. For example, when a concentrated cluster experiences a quality incident, delayed detection and lack of joint contingency planning turn a local problem into a global shortage [1, 7, 9].

Firm-level risk management strategies must therefore be evaluated in light of these systemic drivers. Table 2 summarises the primary strategies discussed in the literature, indicating where they are applied in the supply chain, the benefits they provide, and the barriers that limit their effectiveness.

Table 2: Risk management strategies for API supply chains: implementation focus, benefits, and barriers [1–10]

Strategy	Primary supply chain stage	Expected benefits for APIs	Implementation barriers
Dual/multiple sourcing of APIs	Upstream procurement of APIs and intermediates	Reduced dependence on single facilities or countries; improved bargaining position; shorter recovery time after local disruptions	Limited number of qualified manufacturers; high cost and time of regulatory approval for additional sites; smaller markets with insufficient volume
Strategic API stockpiling	At the marketing authorisation holder or distributor level	Buffer against short-term supply interruptions, especially for highly critical medicines	Working-capital requirements; storage and stability constraints; risk of obsolescence; misalignment with just-in-time incentives
Long-term collaborative contracts	Between API manufacturers, finished-product producers, and, in some cases, public purchasers	Enhanced information sharing, coordinated investment in capacity and quality, and stability of supply	Procurement rules focused on the lowest price, legal and cultural barriers to data sharing, and the fear of antitrust scrutiny
Regionalisation and reshoring of critical APIs	Investment in local or regional production for selected essential APIs	Reduced exposure to distant geopolitical and logistical shocks; shorter lead times; potential industrial policy benefits	High capital expenditure; need for sustained demand and favourable pricing; competition from established low-cost producers
Digitalisation and transparency tools	End-to-end information systems, track-and-trace, real-time monitoring	Earlier detection of emerging shortages, improved demand forecasting, and enhanced regulatory oversight	Fragmented IT systems, data standardisation issues, and a lack of incentives to disclose commercially sensitive data
Risk-based procurement and reimbursement policies	Public payers and insurers	Incorporation of supply resilience into tender evaluation; support for redundant capacity and quality investments	Difficulty in defining measurable resilience criteria; budget constraints; need for cross-country coordination

The tables underline that many strategies require shared financing and risk-sharing arrangements among firms and public actors. For APIs with low margins and high public-health importance, pure market incentives do not justify investment in redundant capacity or reshoring. Policy instruments, such as multi-criteria tenders, advance purchase agreements,

volume guarantees for domestically produced APIs, and international collaboration mechanisms for monitoring and joint mitigation, gain prominence in this setting [6, 7, 9, 10].

From a managerial standpoint, the reviewed literature suggests several directions. First, firms can integrate quantitative risk assessment into supplier selection and portfolio management by adapting multi-criteria decision-making models, such as those proposed by BenAmor et al. [2], to API procurement. Instead of focusing solely on price and the number of suppliers, procurement decisions would weigh geographic diversification, regulatory track record, quality systems, and exposure to shared infrastructure. Second, adopting supply-chain mapping frameworks similar to those of Goswami et al. [4] provides visibility into dependencies hidden behind intermediaries and contract manufacturers. Such maps enable scenario analysis for different disruption types and support the design of targeted safety stocks and dual sourcing, where they create the highest marginal benefit.

Third, company-level measures need to be aligned with sector-level initiatives. The metrics for criticality and resilience proposed by Machta et al. [7] offer a language for dialogue between firms and regulators on which APIs deserve priority interventions and what mix of policies and private actions is appropriate. When combined with empirical evidence from Postma et al. [8] and Socal et al. [9], these metrics can be operationalised into lists of "high-risk" APIs for which stringent monitoring, diversified sourcing, and, where feasible, regional production are encouraged.

For emerging markets, studies by Kashif [5] and Takawira & Mutambara [10] illustrate specific constraints: limited bargaining power vis-à-vis global API suppliers, exposure to currency volatility, underdeveloped regulatory capabilities, and infrastructure gaps. Under such conditions, risk management strategies increasingly intersect with broader development and industrial policy questions—such as support for local API manufacturing, strengthening of regulatory agencies, and regional pooling of procurement and production facilities.

CONCLUSION

The analysis of recent literature reveals that global API supply chains exhibit high economic efficiency but also structural fragility, rooted in geographic concentration, limited transparency, and intense cost pressures. Empirical studies have shown that for many widely used medicines, only a small number of upstream facilities supply APIs, often located in a narrow set of regions. At the same time, multiple finished-dosage manufacturers depend on those same facilities. Risk assessment frameworks and resilience metrics provide tools to quantify these vulnerabilities and to prioritise interventions, but their practical application in industry and policy remains uneven.

The first research task—synthesising structural vulnerabilities—revealed recurrent patterns of concentration, opacity, regulatory heterogeneity, and governance gaps that collectively increase the likelihood and impact of disruptions in API supply. The second task—review of risk assessment and resilience frameworks—highlighted the availability of sophisticated multi-criteria and mapping tools that enable firms and regulators to evaluate exposure across several dimensions, including criticality to health outcomes. The third task—classification and critical examination of risk mitigation strategies—showed that effective risk management relies on a combination of diversification, strategic stockpiling, collaborative contracting, regionalisation of production, digital transparency, and risk-sensitive procurement policies.

For pharmaceutical companies, the findings suggest that procurement and supply-chain functions should integrate formal risk metrics into decision-making, expand visibility beyond immediate suppliers, and engage in structured dialogue with regulators regarding critical APIs. For policymakers, the results support the design of instruments that reward resilience in tenders, facilitate investment in redundant and regional capacity for essential APIs, and

strengthen international coordination on monitoring and response to disruptions. Taken together, these measures contribute to more robust API supply chains and, consequently, to more stable access to medicines in both high-income and emerging markets.

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