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Blockchain Technology in Pharmaceutical Supply Chains: A Feasibility Assessment in Nepal

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Abstract:

Substandard and falsified medicines remain a major public health concern in low- and middle-income countries (LMICs), with Nepal facing significant challenges due to its import-dependent pharmaceutical supply chain and limited traceability mechanisms. Nepal recorded hundreds of drug recalls over the past decade, while studies indicate that a notable proportion of essential medicines fail quality standards. This study presents the first Nepal-specific blockchain feasibility assessment, examining the viability of adopting blockchain technology to improve transparency and traceability in Nepal's pharmaceutical supply chain. Drawing on secondary data analysis and a narrative literature review of 28 indexed sources published between 2020 and 2025, consulted across databases including PubMed, Scopus, Google Scholar, and institutional repositories (WHO, ITU, DDA, MTaPS), blockchain feasibility was evaluated across five dimensions: technical suitability, digital infrastructure readiness, regulatory and governance environment, economic feasibility, and stakeholder ecosystem. The findings indicate that blockchain is technically well-suited (rated High) to Nepal's supply chain challenges, while digital infrastructure readiness is Moderate. Regulatory and governance capacity, economic feasibility, and stakeholder ecosystem readiness are currently rated Low to Low-Moderate, representing the primary barriers to implementation. The study concludes that blockchain adoption should follow a phased approach supported by regulatory reform, capacity building, and pilot projects, and proposes a practical implementation roadmap for Nepal.

Keywords: *blockchain technology; counterfeit medicines; digital governance; drug traceability; pharmaceutical supply chain; regulatory governance*

1. Introduction:

Each year, hundreds of thousands of people die from substandard and falsified medicines, with deaths concentrated in LMICs where regulatory controls are weakest. Between 2017 and 2021, the WHO Global Surveillance and Monitoring System recorded 877 such cases, with incidence rates increasing more than threefold annually (WHO, 2024). Nepal is particularly vulnerable: since 2010, the Department of Drug Administration (DDA) has recalled 346 pharmaceutical products at an exponentially growing rate (Neupane et al., 2022), and Nepal sits between two of the world's largest sources of falsified healthcare products (Bhandari & Rayamajhi, 2022). Pharmaceutical supply chains generate

complex transactional data across multi-actor networks that are difficult to verify, readily manipulated, and rarely shared across organizational boundaries (Wong et al., 2023). Paper-based and siloed digital systems cannot deliver the traceability required to detect fraud or support timely regulatory responses, deficiencies compounded in Nepal by fragmented regulation, inadequate digital infrastructure, and intermediaries with limited incentives for transparency (Nabli et al., 2025).

Blockchain technology has emerged as a structurally distinct response. Its decentralized, immutable, cryptographically secured ledger enables participants to authenticate transactions without relying on a single trusted authority; smart contracts automate rule enforcement; and IoT integration enables real-time environmental monitoring (Damar et al., 2025). Evaluated through the 4D framework, pharmaceutical supply chain traceability consistently ranks among blockchain's strongest use cases (Gaynor et al., 2024). Permissioned architectures such as Hyperledger Fabric offer fine-grained access control and auditability suited to regulated sectors (Mezquita et al., 2023). The Verifiable Supply Chain Credentials (VSCC) framework and PharmaChain both propose governance structures combining on-chain/off-chain data management with smart contract compliance monitoring, though both remain largely at the simulation or theoretical stage (Gomasta et al., 2023; Mezquita et al., 2023).

The strongest empirical evidence comes from the MediLedger DSCSA Pilot Project in the United States, which demonstrated consortium-based end-to-end traceability under Drug Supply Chain Security Act requirements (MediLedger Project, 2020). However, its success depended on institutional commitment, mature digital infrastructure, and a clear regulatory mandate—conditions absent in most low-resource environments. Reviews of adoption barriers identify technical constraints (scalability, smart contract enforceability), organizational resistance from intermediaries dependent on information asymmetry, and regulatory gaps, including the absence of legal frameworks for blockchain-based evidence (Ghadge et al., 2023; Zakari et al., 2022). Critically, however, these barriers are rarely disaggregated by institutional context: a barrier taxonomy derived predominantly from high-income settings systematically underestimates the foundational nature of governance deficits in LMIC environments, where regulatory infrastructure itself—not merely its digital extension—is absent or nascent. Governance tensions between blockchain immutability and data minimization obligations under HIPAA and GDPR remain legally unresolved in most jurisdictions (Shine et al., 2023). More ambitious Pharma 4.0 models that integrate blockchain with AI and IoT presuppose digital maturity that is found in virtually no low-income market (Wong et al., 2023).

Research on blockchain in LMIC healthcare has grown but remains predominantly descriptive. More recent work identifies infrastructure deficits and regulatory risk as the primary barriers, with hybrid adoption models and phased regulatory sandbox approaches proposed as more viable entry points than full-system replacement (Joshi & Sharma, 2023; Prasad, 2025). Nepal is absent from this literature despite representing a paradigmatic case of regulatory vulnerability and institutional underdevelopment. The barriers facing a Kathmandu-based pharmaceutical distributor are qualitatively distinct from those in high-income settings, yet the literature rarely disaggregates them by institutional context (Lahjouji et al., 2023). This study is theoretically situated within the Technology-Organization-Environment (TOE) framework, which holds that technology adoption is shaped by three interdependent contexts: the technological characteristics of the innovation itself, the organizational capacity available to deploy it, and the broader environmental conditions—regulatory, infrastructural, and institutional—within which adoption occurs. The TOE framework has been identified as a key theoretical lens for studying blockchain

adoption determinants in supply chain settings (Vu et al., 2023). Applied to Nepal's pharmaceutical sector, the framework directs analytical attention toward regulatory institutional capacity and governance infrastructure as the primary determinants of feasibility, a framing the evidence in this study consistently supports.

This study addresses three gaps: the absence of any empirical blockchain feasibility assessment for Nepal; the failure of barriers literature to contextualize obstacles by institutional setting; and the lack of implementation roadmaps evaluated against South Asian regulatory realities. Three research questions are addressed: (i) What blockchain platforms and frameworks have been applied to pharmaceutical traceability, and what does evidence indicate about their effectiveness? (ii) What barriers constrain blockchain adoption in low-resource settings, particularly in South Asia? (iii) What conditions must be met for viable blockchain adoption in Nepal's pharmaceutical supply chain?

2. Methodology:

This study employs secondary data analysis combined with a narrative literature review. The narrative review approach was selected because Nepal has no existing pharmaceutical blockchain application, making secondary data analysis and structured evidence synthesis the most appropriate and methodologically established approach for a context-specific feasibility assessment of this kind (Joshi & Sharma, 2023; Nabli et al., 2025). Literature was identified through searches of PubMed, Scopus, Google Scholar, and institutional repositories (WHO, ITU, DDA, MTaPS), using search terms including blockchain, pharmaceutical supply chain, drug traceability, counterfeit medicines, LMIC, Nepal, digital health governance, and feasibility assessment. Sources were included if they were indexed, contained original data or analysis relevant to Nepal's pharmaceutical system or digital infrastructure, and were published between 2020 and 2025; sources outside this window were included only where they represented foundational frameworks or seminal empirical pilots (e.g., MediLedger Project, 2020). Approximately 28 sources met these criteria and informed the analysis. Given the narrative review design, a PRISMA flow diagram was not applied; the source selection process is described in full above. Data were drawn from five source categories: DDA recall databases as analyzed by Neupane et al. (2022) and Barma et al. (2025); nationwide essential medicine quality testing data from Dhakal et al. (2023), published in PLOS Global Public Health; digital infrastructure data from the ITU (2024) and DataReportal (2025); DDA institutional capacity assessments from USAID MTaPS programme evaluations (2021–2024); and pharmaceutical trade and import data from NEPSE Trading (2026) and Pharmabiz (2024).

Analysis proceeded in two phases: an empirical profile of Nepal's supply chain challenges (Section 3), followed by a structured feasibility assessment using the five-dimensional framework of Spencer-Hicken et al. (2023) applied to Nepal-specific evidence (Section 4). Each dimension was rated as High, Moderate, Low, or Conditional by mapping the available Nepal-specific evidence against the enabling conditions and risk indicators defined for that dimension in the Spencer-Hicken et al. (2023) framework. Ratings represent analytical judgements grounded in the evidence reviewed, rather than quantitative scores, consistent with the framework's intended application to novel or data-limited contexts. Limitations include the absence of primary stakeholder fieldwork, the DDA database's lack of denominators for calculating prevalence rates, and the national-level aggregation of infrastructure data, which obscures urban-rural disparities. Primary qualitative research with DDA officials and supply chain stakeholders is identified as a high-priority follow-up. To support validity, all empirical claims were drawn exclusively from indexed, peer-reviewed sources or official institutional datasets; cross-source triangulation was applied where multiple independent studies reported on the same indicator.

3. Results and Discussion:

Pharmaceutical Quality Challenges in Nepal

Pharmaceutical quality failure in Nepal is chronic and deteriorating. A review of the DDA recall database from 2010 to 2020 identified 346 recalled products, with recall rates increasing markedly over the decade: 62% were substandard, 11% falsified, and 27% unregistered (Neupane et al., 2022). The proportion of recalled imported products (42.2%) was comparable to domestically manufactured ones (40.7%), indicating failures across both supply streams. Beyond 2020, a retrospective study of DDA notices from April 2023 to May 2025 identified 50 further recalls, with assay failure the most common basis (34%), and 40% of cases cited non-compliance with the Indian Pharmacopoeia 2022 (Barma et al., 2025). Independent testing corroborates this: a 2023 national cross-sectional study across 62 health facilities in all seven provinces found that 37 of 244 essential medicine batches (15.16%) failed pharmacopeial standards, with 62.16% of failures originating from government-supplied medicines (Dhakal et al., 2023; Ghimire, 2025). Key indicators are presented in Table 1.

Table 1. Nepal Pharmaceutical Quality Failure Data (Key Indicators)

Indicator	Value	Source
Total drug recalls, 2010–2020	346 products	(Neupane et al., 2022)
Annual recall trend	Significant increase over the decade	(Neupane et al., 2022)
Proportion substandard	62%	(Neupane et al., 2022)
Proportion falsified	11%	(Neupane et al., 2022)
Proportion unregistered	27%	(Neupane et al., 2022)
Recalls, April 2023–May 2025	50 products in 2 years	(Barma et al., 2025)
Recalls due to assay failure	34%	(Barma et al., 2025)
Essential medicine batches failing pharmacopeial standards	37/244 batches (15.16%)	(Dhakal et al., 2023)
Failures from government-supplied medicines	62.16% of all failures	(Ghimire, 2025)

Structural Vulnerability of Nepal's Pharmaceutical Supply Chain

Nepal imports 55% of its medicines, approximately 58% of which originate from India, which itself sources around 70–72% of its active pharmaceutical ingredients from China (NEPSE Trading, 2026; Pharmabiz, 2024). This layered cross-border chain creates multiple upstream points of vulnerability beyond Nepal's regulatory reach. China and Hong Kong account for 31% of globally detected falsified medicines, and India has acknowledged widespread domestic quality deficiencies (Ghimire, 2025). Domestically, over 27,000 pharmacies and 5,000 wholesalers operate under regulations not substantively updated between 2014 and 2023, with no end-to-end traceability mechanism, and each stage of the chain operating predominantly on paper or through non-interoperable digital systems (The Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, 2024a). This is the configuration blockchain is structurally designed to address.

Regulatory and Institutional Readiness

The DDA, established under the Drug Act of 1978, is Nepal's sole national medicines regulatory authority. As of 2021, it had no operational Quality Management System: only 24% of DDA and National Medicines Laboratory staff had completed introductory QMS training, and just eight had completed ISO 9001:2015 auditor training (The Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, 2021). A large registration backlog had also accumulated due to understaffing (The Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, 2024b). Since 2021, incremental reforms have occurred with MTaPS support: 100 backlogged products were cleared between July 2021 and April 2022, and Nepal's first-ever Good Pharmacy Practice (GPP) and Good Storage and Distribution Practice (GSDP) guidelines were issued in July 2023, though an assessment of 39 pharmacies and 30 wholesalers found significant non-compliance with GSDP criteria, including quality management, qualified personnel, and safe transportation (The Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, 2024a). The Drug Act of 1978 predates all digital technologies and would require amendment to recognize blockchain-based compliance records legally. A permissioned blockchain governance model requires an institution capable of credentialing network members and enforcing smart contract rules—a capacity the DDA is building but has not yet established.

Blockchain Feasibility Assessment:

Using the framework of Spencer-Hicken et al. (2023), this section assesses the feasibility of blockchain in Nepal's pharmaceutical sector across five dimensions, each rated as High, Moderate, Low, or Conditional.

Technical Suitability

Nepal's supply chain failures—inability to verify pharmaceutical authenticity across multi-tiered imports, absence of tamper-proof record-keeping, and inadequate recall traceability—correspond directly to problems blockchain is designed to address. An immutable ledger would cryptographically record every transaction from manufacturer to pharmacy, making tampering detectable (Mezquita et al., 2023). Smart contracts can automate compliance checking at each handover (Conway et al., 2022), and IoT integration enables real-time environmental monitoring relevant to Nepal's documented recall categories (Authena, 2023). The 4D framework identifies counterfeit medicine prevention and traceability as among blockchain's strongest use cases (Gaynor et al., 2024), rating: High**.** Nepal's failure profile maps more closely to MediLedger's pre-implementation context than to settings where blockchain failed, because the core problem is authentication rather than data volume.

Digital Infrastructure Readiness

Nepal's mobile cellular coverage reaches 98.3% of the population, with 88% having 4G access and mobile broadband penetration at 94.5%, comparable to the global average (ITU, 2024). These figures support a permissioned, mobile-first urban deployment. However, internet user penetration stands at only 55.8%, 77% of the population is rural (DataReportal, 2025), fixed broadband costs at 7.2% of GNI per capita far exceed the UN target of under 2%, and Nepal has no 5G network for IoT-intensive applications (ITU, 2024), rating: Moderate**.** Urban centers are ready; a broader rollout requires phased architectural design and financial support. Unlike high-income settings where full fixed-broadband coverage supports IoT-intensive deployment, Nepal's infrastructure profile positions it closer to other South Asian LMIC pilots that have succeeded with mobile-first, urban-hub architectures (Joshi & Sharma, 2023).

Regulatory and Governance Environment

This is the binding constraint. A permissioned blockchain requires an institution capable of credentialing members, validating transactions, and enforcing smart contract rules. The DDA currently lacks an ISO-certified QMS; its first national good practice

guidelines were issued only in 2023, with implementation still incomplete (MTaPS, 2024a); and the Drug Act of 1978 provides no legal basis for blockchain-based compliance records. Blockchain can support regulatory enforcement, but it cannot create institutional capacity that does not yet exist, rating: Low(currently), Conditional (medium-term, subject to DDA QMS completion, Drug Act revision, and blockchain governance framework development). This distinguishes Nepal sharply from MediLedger's operating context, where a pre-existing federal regulatory mandate and digitally mature institutions enabled blockchain governance from day one; Nepal's DDA is not yet that institution.

Economic Feasibility

Nepal's 109 licensed pharmaceutical manufacturers and over 5,000 wholesalers are predominantly small-scale operators with limited capacity to absorb deployment costs (DDA, 2023). Requiring simultaneous cost contributions from all stakeholders would exclude smaller actors and create traceability gaps. Viable implementation requires a phased cost-sharing model in which the DDA and major importers bear initial costs, or donor grant financing, rating: Low (short-term, absent subsidy or donor funding), Moderate (medium-term, under a structured public-private financing scheme). Cost barriers in Nepal are structurally more severe than in comparable LMIC pilots in India and Bangladesh, where larger industry bases enabled cost-sharing models that are not yet viable in Nepal's predominantly small-scale market (Joshi & Sharma, 2023).

Stakeholder Ecosystem

Pharmaceutical blockchain effectiveness depends on comprehensive participation: the MediLedger pilot demonstrated that traceability gaps appear wherever a supply chain actor is absent from the network (MediLedger Project, 2020). Nepal's ecosystem—manufacturers, importers, numerous small wholesalers, hospitals, government clinics, pharmacies, and the DDA—presents considerable coordination complexity. Major importers and urban wholesalers already engaging with the DDA's Pharmadex system are the most feasible entry points. Rural pharmacies and smaller wholesalers present greater challenges due to limited digital literacy and connectivity. Incumbent intermediaries whose market advantages depend on information asymmetry have strong incentives to resist a transparent system, a barrier consistently underestimated in developing-economy implementations (Ghadge et al., 2023), rating: Low-Moderate, variable by stakeholder type; urban institutional actors are feasible entry points; rural and informal sector participants require dedicated strategies. The intermediary resistance identified here is qualitatively stronger than in food supply chain blockchain pilots, where participants had commercial incentives to join; Nepal's pharmaceutical intermediaries face the opposite incentive structure.

Proposed Implementation Pathway

Table 2. Consolidated Blockchain Feasibility Assessment for Nepal's Pharmaceutical Supply Chain

Dimension	Current Rating	Key Constraint	Required Enabling Condition
Technical Suitability	**High**	None – strong fit	No additional preconditions
Digital Infrastructure	**Moderate**	Rural connectivity; high fixed broadband cost	Mobile-first node architecture; urban hub phasing
Regulatory & Governance	**Low → Conditional**	No QMS; no digital records law; no blockchain framework	DDA QMS completion; Drug Act revision;

			governance model development
Economic Feasibility	**Low → Moderate**	High deployment costs; limited industry capacity	Phased public-private financing; donor grant support
Stakeholder Ecosystem	**Low-Moderate**	Intermediary resistance; rural digital literacy gaps	Regulatory mandate; pilot with urban institutional actors

Table 2 shows that blockchain is a strong technical fit for Nepal's pharmaceutical sector but successful adoption depends on prior institutional and regulatory readiness.

A three-phase pathway is proposed. Phase I (Years 1–3): DDA QMS completion and ISO 9001:2015 certification; Drug Act amendment to recognize digital supply chain records; blockchain governance framework development with MTaPS and WHO support; and a controlled pilot with three to five major Kathmandu importers on Hyperledger Fabric. Phase II (Years 3–5): expansion to urban wholesale and hospital procurement networks; integration with the Pharmadex registration system; and smart contract deployment for high-risk categories (antimicrobials and injectables, which constitute the majority of DDA recalls). Phase III (Years 5–10): rural extension via mobile-first lightweight nodes, subsidized participation for smaller pharmacies, and linkage with Nepal's national health information system.

The literature confirms that blockchain offers genuine structural advantages for pharmaceutical traceability, as demonstrated by the MediLedger DSCSA Pilot and architecturally supported by systems such as PharmaChain (Gomasta et al., 2023; MediLedger Project, 2020). The critical qualification is that all successful implementations occurred in high-income, high-infrastructure environments with pre-existing regulatory mandates and digitally mature supply chains (Ghadge et al., 2023). Blockchain amplifies the governance capacity of the institutions that deploy it; it cannot substitute for absent capacity.

The Nepal context demonstrates that barriers in low-resource settings are qualitatively different—not merely scaled-down. The DDA's lack of a functional QMS until at least 2021, the recency of its first good practice guidelines (2023), and the pre-digital Drug Act of 1978 collectively indicate a regulatory environment that lacks the institutional scaffolding presupposed by any blockchain governance model—the primary distinguishing factor from MediLedger-type settings, and one systematically underweighted in barriers taxonomies that aggregate across disparate contexts (Ghadge et al., 2023). Nepal's mobile broadband penetration of 94.5% suggests connectivity is surmountable for an urban-first deployment (ITU, 2024), but 77% rural population and high broadband costs define clear boundaries for an initial implementation phase (DataReportal, 2025; ITU, 2024). The layered import dependency—55% of medicines from India, itself importing 70% of APIs from China—underscores both the urgency of cross-border traceability and the governance complexity any implementation must navigate (NEPSE Trading, 2026; Pharmabiz, 2024).

The feasibility assessment identifies a sequenced set of enabling conditions: DDA QMS completion and ISO certification as the foundational institutional precondition; Drug Act revision to legally recognize digital supply chain records and smart contract monitoring; and a public-private or donor financing mechanism enabling major importers to bear initial costs while smaller operators participate on a subsidized basis. From a theoretical perspective, the core finding is that the primary barrier is institutional rather than technological. This conclusion applies beyond Nepal to any

LMIC pharmaceutical distribution context in which blockchain is considered without commensurate investment in regulatory infrastructure: institutional investment must precede technology investment.

4. Conclusion:

This paper argues that Nepal is facing a continuously worsening systemic crisis of pharmaceutical quality. Between 2010 and 2025, 396 drugs have been recalled, with the recall rate climbing year on year. 15.16% of essential medicines fail to meet quality standards, and most of these substandard products originated from official supply channels (Barma et al., 2025; Dhakal et al., 2023; Ghimire, 2025; Neupane et al., 2022). While blockchain technology is well-suited to address the core structural flaws at the root of this crisis, institutional constraints currently preclude viable implementation. The central conclusion is that blockchain is technically ready; the institutional environment is not.

The right response is to invest in enabling conditions—regulatory capacity-building, legislative reform, and phased piloting with urban institutional actors—rather than premature full-scale deployment. This study offers the first structured feasibility assessment of blockchain for Nepal's pharmaceutical supply chain, providing a replicable analytical framework and actionable guidance to policymakers and international development partners. Future research should focus on qualitative fieldwork with DDA officials and supply chain stakeholders, as well as comparative analysis with analogous South Asian LMIC settings such as Bangladesh and Sri Lanka.

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Competing Interests:

The authors declare no competing interests.

Ethical Considerations:

This study utilized only secondary data obtained from publicly available institutional sources and published peer-reviewed literature. No human participants, personal data, or confidential information were involved in the research. Consequently, ethical approval and informed consent were not required.

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