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Ensuring Drug Authenticity: A Blockchain-Based Framework for Drug Supply Chain Traceability and Forensics

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ABSTRACT

The spread of counterfeit and substandard drugs is a major global health and economic problem especially in the developing world. This paper introduces a drug authentication and registration system using blockchain which aims to establish greater transparency, security and trust in the pharmaceutical supply chain. Using the platform of Hyperledger blockchain, smart contracts, decentralised applications (dApps), and APIs, the system will automate the drug registration process, the process of drug verification, and tracking. The drug information added by the manufacturer, such as name, form, expiry date, manufacturing date, and use instructions, are inseparably stored in the blockchain. With the successful registration and execution of a smart contract, a unique barcode is automatically created by the system that allows consumers to check the authenticity of drugs with the help of mobile devices. In order to be robust, the design will include both hardware (servers, nodes, mobile devices, barcode scanners, and encryption hardware) and software (smart contracts, APIs, analytics tools, and user interfaces) requirements. The results indicate that the system effectively logs and authenticates drugs in real time and the audit trail is immutable and cannot be tampered with by even the drug manufacturers. The blockchain-based architecture also leads to a higher level of traceability, mitigating the impact of a counterfeit distribution, and increasing user confidence through correct and disclosed verification. The adoption has shown that blockchain technology can play a major role in enhancing the fight against fake drugs.

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INTRODUCTION

The Global Issue of Counterfeit Drugs

The spread of fake drugs is a key health and economic issue around the world. The World Health Organization (WHO) estimates that at least one out of ten medical products in low- and middle-income countries is substandard or falsified leading to high morbidity, mortality, and financial loss (Asrade Mekonnen et al., 2024; World Health Organization, 2024). The fake drugs are deadly pharmaceuticals like antibiotics and antimalarial drugs as well as routine over-the-counter drugs, compromising healthcare systems and undermining the trust of people (Wosu et al., 2025). In addition to hurting humans, the financial cost is also significant, as the global pharmaceutical counterfeit market is estimated at more than 200 billion dollars a year, which is one of the most profitable criminalactivities (Schwarz et al., 2024). The conventional pharmaceutical supply chain is based on centralised models, which are often not transparent, traceable, or tamper-resistant, thus allowing counterfeit prescription drugs to penetrate legitimate markets without detection (Chandras et al., 2023; Kavita Kumari, 2019).

The Role of Blockchain Technology

New digital technologies can provide a solution to such vulnerabilities. Blockchain technology has emerged as one of them as a transformational enabler of safe and transparent supply chains (Kumarswamy & Sampigerayappa, 2024). Its decentralised nature, immutable registry, and cryptographic assurances render it to be quite suitable to monitor the provenance and authenticity of pharmaceuticals within the multifaceted distribution chains (Dogruer Erkok et al., 2026; Yli-Huumo et al., 2016). By making all transactions auditable, centralised, and easy to verify by numerous parties, blockchain has removed the need to rely on centralised organisations to take care of transactions, thus minimising the chances of manipulation and fraud (Padma & Ramaiah, 2024). The integration of Hyperledger Fabric with decentralised drug traceability has been shown to be achieved in recent works, like PharmaChain, which guarantees the real-time verification of provenance by eliminating reliance on middlemen (Gomasta et al., 2023). Likewise, vaccine management systems based on blockchain and smart contracts, like Vacledger, can demonstrate how compliance, stock tracking, and cross-border compliance can be automated using smart contracts to reduce the circulation of fake vaccines (Vo et al., 2025).

Current Implementations and Limitations

(Oluwafemi et al., 2021) noted that authorised blockchain architecture, pharmaceutical authentication has been investigated on the Ethereum-based solutions. They can also include IoT sensors, QR-code labelling, and environmental surveillance, allowing real-time monitoring of the conditions in a storage and distribution environment and empowering the end-user to confirm the drug authenticity (Haque et al., 2024). These integrations demonstrate how blockchain can help not only protect supply chains but also act as a means of forensics to trace an incident following it, leaving the regulators and law enforcement with an unaltered trail (Bhuvaneshwari et al., 2025). Notwithstanding such advantages, the use of blockchain in pharmaceutical is still in its infancy (Riedel, 2024). Most of the implementations are only done in prototypes or small-scaled pilots with little assessment of scalability, privacy, and interoperability issues (Bapatla et al., 2023)

Gaps, Challenges, and Proposed Solutions

(Agarwal et al., 2024) identified a large research gap is the physical digital binding problem where physical items can remain manipulated by corrupting by counterfeiters despite the safety of electronic documentation. To deal with this, (Cit et al., 2024) have tested IoT-powered seals, NFC tags, and Physically Unclonable Functions (PUFs) to guarantee more secure connections between the body of the physical product and the blockchain entries (Chen et al., 2020). Nevertheless, the safety of IoT devices per se is also a subject of concern since insecure sensors can create new security issues that will negatively affect the overall trust model. Moreover, pharmaceutical supply chains across the globe are extremely fragmented, covering various jurisdictions, manufacturers, distributors and regulators (Kumar et al., 2025). Another level of complexity is the need to ensure that blockchain solutions are interoperable with legacy healthcare information systems and that these solutions comply with various regulatory frameworks, including the U.S. Drug Supply Chain Security Act (DSCSA) and the EU Falsified Medicines Directive (FMD) (Musamih et al., 2021). Contrary to the current solutions that mostly involve traceability, the framework proposed puts more focus on forensic reconstruction and regulatory compliance, making it a more holistic approach to protecting pharmaceutical ecosystems.

Context in Developing Countries and Broader Implications

The issue of counterfeit and substandard drugs remains a major global health and economic concern. According to a study conducted by (Wagiealla et al., 2022) the prevalence of counterfeit medicines in developing countries, especially in Africa, is very high, and the lack of proper regulatory control over the situation, the low level of public awareness, and the lack of control over the supply chain are the main factors contributing to the situation. (Hajleh et al., 2021) have noted that customer buying habits and preference of the brand play a significant role in drug choices, and this poses a weak link to the counterfeiters to take advantage of, particularly in situations where trust in generics is minimal. In third world countries, (Abunike & Ibe, 2025) emphasised how lax regulatory systems, porous supply chains, and inadequate enforcement mechanisms have developed the industrial heartlands in Africa into counterfeit drug manufacturing hotspots, with serious impacts on the general public health and the economy. Similar difficulties were observed by (Khangan & Tiple, 2025) in India, in which lack of quality control and unlawful distribution channels contribute to the counterfeit crisis. On a more general note, (Friedman & Ciccarone, 2025) outlined the increasing danger of fake pills that can cause avoidable mortality and deteriorating mistrust towards the health care systems. All of these investigations highlight the critical importance of providing secure, transparent, and technologically sophisticated systems including blockchain-based forensic models that will be needed to ensure the integrity of the pharmaceutical supply chains and the health of the global population. Counterfeit drugs still find their way to the supply chains across the globe compromising patient safety and treatment effectiveness as well as trust in medical systems.

Flaws in Current Pharmaceutical Supply Chains

The current pharmaceutical supply chains are mostly centralised and are thus susceptible to manipulation of data, loss of transparency, and lack of auditability (Said et al., 2023). Besides, any form of authentication, including barcodes, holograms, or RFID tags, can be altered, duplicated, or hacked, and it leaves large gaps in the means of counterfeiting (Aulia et al., 2024). Despite the indication of blockchain technology concerning better supply chain visibility, the majority of current applications are based on proof-of-concept prototypes or have a limited scope (Dhingra et al., 2024). Several solutions have to deal with extreme difficulties like the scale problem, the interoperability problem with legacy healthcare infrastructure, the regulatory framework problem, and the problem of physical, digital mismatch, including where fake products can be replaced by far even with digital records intact (Bapatla et al., 2023; Chen et al., 2020). This leaves a research need: how to construct a blockchain-enforced forensic system that can deliver end-to-end pharmaceutical provenance, with auditability that cannot be tampered with, and the ability to detect counterfeits reliably and at scale, be interoperable, and be regulatory-compliant.

The Urgency of Combating Counterfeit Drugs

This study has been driven by the fact that it is necessary to fight the menace of counterfeit pharmaceuticals that have become alarming percentages worldwide. (World Health Organization, 2024) reports that falsified and substandard medications are widespread in almost every part of the globe, and developing nations are affected at a disproportionately higher rate since many regulatory rights and chain of supply management are not as strong (Tegegne et al., 2024). Not only do these fake products lead to treatment failure, drug resistance, and preventable deaths, but also lead to economic losses of billions of dollars per year due to a lack of trust in healthcare systems and subsequent financial losses (Asrade Mekonnen et al., 2024; Nayyar et al., 2015). Old forms of preventing counterfeiting, including barcodes, holograms, and RFID systems, are now inadequate because they can be easily manipulated, copied, and cannot interoperate with a variety of actors in a supply chain (Chen et al., 2020).

Blockchain as a Potential Solution

The decentralised, immutable and transparent architecture of blockchain technology offers a distinct chance to overcome these problems. With the integration of IoT equipment, labeling by QR-codes, and smart contracts, blockchain can be used to build end-to-end forensic systems to guarantee provenance, authenticity, and traceability of pharmaceuticals (Haque et al., 2024; Seun Adeyemo et al., 2024). This study is thus driven by the need to put these technological advances in place to develop scalable, secure, and regulatory compliant blockchain to ensure patient protection, enhance pharmaceutical supply chains and regain confidence in health systems (Chijioke M et al., 2024).

MATERIALS AND METHODS

The presented counterfeit pharmaceutical detection system is developed on the basis of Hyperledger Fabric, which is a permissioned blockchain platform that is focused on application within enterprises. The Hyperledger Fabric is an efficient and adaptable platform to develop solutions based on blockchains using its modular structure, pluggable consensus benefits, and network design flexibility ("Threats of Trade in Counterfeit Pharmaceutical Products," 2022). This allows the application of Hyperledger Fabric in areas like supply chain management, healthcare and finance, where security, scalability, and regulatory compliance are critical. The proposed system will enable an end-to-end traceability, tamper-proof auditability, and increased counterfeit drug detection through these features, with the privacy and security requirements of pharmaceutical stakeholders intact. The proposed model is shown in Figure 1.

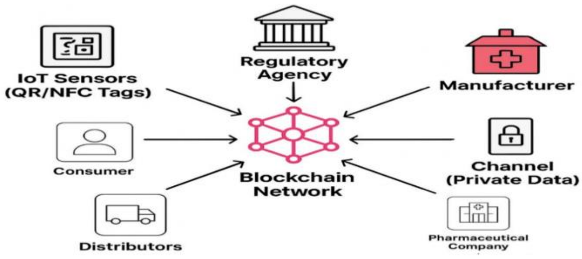

Figure 1**:** The Proposed System Architecture

Figure 1 shows the flow of a pharmaceutical supply chain on Hyperledger Fabric, a permissioned blockchain network with manufacturers, distributors, pharmacies, and regulators as the actors. Chaincode (also known as smart contracts) ensure compliance of counterfeit detection, and IoT sensors QR/NFC tags verify the product in real-life. The code allows consumers to validate authenticity, which ensures end-to-end traceability and is forensically auditable.

Mathematical Model of the Blockchain-Based Drug Authentication System

Notation and Sets

Let the system be defined over the following sets and functions:

M — set of manufacturers.

D — set of drug units (each representing a distinct physical package).

N — set of blockchain nodes (peers + orderers), with$|N| = N$.

U — set of users (consumers, pharmacies, regulators).

T — set of transactions recorded on the blockchain ledger.

t — time index (continuous or discrete).

Hash (·) — collision-resistant cryptographic hash function.

Sign 〖_k〗 (x) — digital signature of message $x$using private key$k$.

Verify 〖_K〗 (x, sigma) — verification of signature σunder public key$K$.

CC — smart contract (chaincode) functions deployed on the blockchain.

δ — allowable tolerance threshold for IoT sensor readings (e.g., temperature limits).

State and Record Structure

Each drug unit $d \in D$is represented by a registration record: $R_d = (ID_d, meta_d, TS_d, \sigma_d)$

Where: ID_d— unique manufacturer-assigned drug identifier.

$meta_d$— Metadata vector: $meta_d =$ (name, form, batch, MFG, EXP, usage)

TS_d— Timestamp of registration.

σ_d— Manufacturer signature computed as: $\sigma_d = \text{Sign}_{k_m}(\text{Hash}(ID_d \parallel meta_d \parallel TS_d))$

The block chain stores a transaction: $\tau_d = (\text{Hash}(R_d), meta\_ptr_d, TS_d, K_m, \sigma_d)$

Where: meta_ptr $_d$ — pointer to off-chain data (IPFS / database).

K_m— Manufacturer public key.

Binding Barcode / QR Code to Blockchain Record

Each drug unit receives a verifiable barcode: $B_d = \text{Enc}_{k_{sys}}(\text{Hash}(R_d))$

Or a simplified public form: $B_d = \text{Base64}(\text{Hash}(R_d) \parallel ID_d)$

The barcode encodes a verification token: $\tau_{\text{token}} = f(\text{Hash}(R_d))$

This token allows the system to match the scanned barcode to the ledger entry.

Registration Operation (Smart Contract Logic)

When a manufacturer $m \in M$ registers a drug unit$d$:

Construct the data recordR_d.

Compute the hash: $h_d = \text{Hash}(R_d)$

Form transactionτ_d.

Invoke: $CC.Register(\tau_d)$

The blockchain executes endorsement + ordering + commit.

A registration is successful iff: $\exists\, \tau_d \in T: \tau_d.hash = h_d \ \wedge \ \text{Verify}_{K_m}(h_d, \sigma_d) = \text{true}$

Verification Operation (User Scan Routine)

When a user $u \in U$scans the barcode $B_d$and obtains tokentkn:

$$\text{Verify}(tkn) = \begin{cases} \text{"Original"}, & \text{if } \exists \tau \in T: \tau.hash = f^{-1}(tkn) \\ \text{"Fake"}, & \text{otherwise} \end{cases}$$

Full authenticity requires: $\text{Hash}(R_d) = \tau.hash \wedge \text{Verify}_{K_m}(\tau.hash, \sigma_d) = \text{true}$

This ensures tamper-proof verification, preventing alteration of either the drug data or the QR code binding.

Ledger Growth Model

Let:

λ_r= average rate of registration transactions (records/sec).

s_r= average size of each on-chain transaction (bytes).

Then the ledger growth rate is: $G = \lambda_r \cdot s_r$(bytes/sec)

Total ledger size after time$T$: $S(T) = S(0) + G \cdot T$

For hybrid systems (majority stored off-chain): $s_m \ll s_r$

Thus: $G_{\text{hybrid}} = \lambda_r \cdot s_m$

Significantly improving block chain scalability.

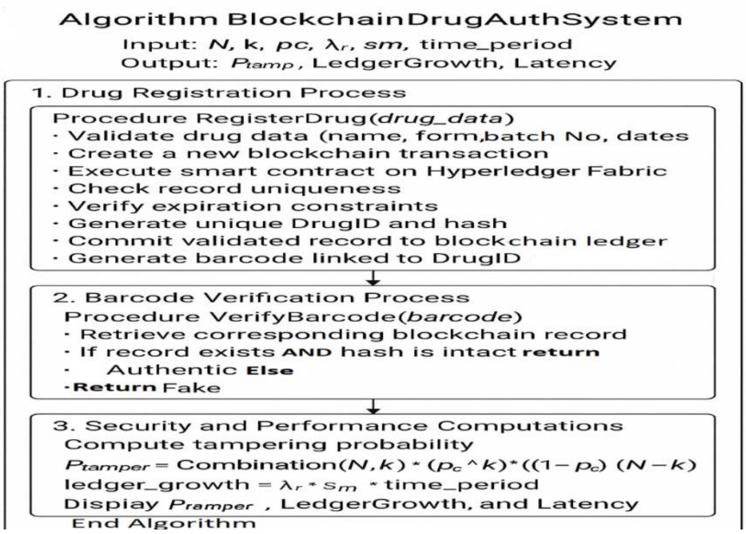

Figure 2: Algorithm Blockchain Drug Authentication System

The algorithm computes three key system performance metrics

Tampering Probability (P_tamper):
$P_{tamper} = \binom{N}{k} \cdot p_c^k \cdot (1 - p_c)^{N-k}$
This expresses the likelihood that an attacker can compromise enough nodes (k) in the network to falsify blockchain data. A higher N and larger k reduce this risk, improving system security.
Ledger Growth: $ledger_{growth} = \lambda_r \cdot s_m \cdot time_{period}$
This calculates how quickly the blockchain storage expands based on how many drugs are registered and how much metadata is stored per record. It helps in planning storage and scalability strategies.
Latency: $latency = BaseLatency + NetworkDelay \cdot \binom{N}{k}$
Here, transaction latency increases when more nodes validate the transaction. Increasing k (endorsement threshold) improves security but may increase transaction time, requiring a balance between performance and trust.
Finally, the algorithm outputs P_tamper, ledger_growth, and latency to help evaluate how secure, scalable, and efficient the system is.

Blockchain-Based Registration and Verification Process
Figure 3 illustrates a blockchain-based drug authentication process where drug details such as name, form, batch number, and manufacturing/expiry dates are first registered and hashed on the blockchain with a digital signature for tamper resistance. A cryptographic hash is then encoded into a QR or barcode and printed on the drug package. When scanned by users or regulators, the system retrieves the corresponding blockchain record and verifies the integrity of the stored hash. If the scanned information matches the blockchain entry, the drug is confirmed as "Original"; otherwise, it is flagged as "Fake," ensuring secure and reliable verification throughout the supply chain.

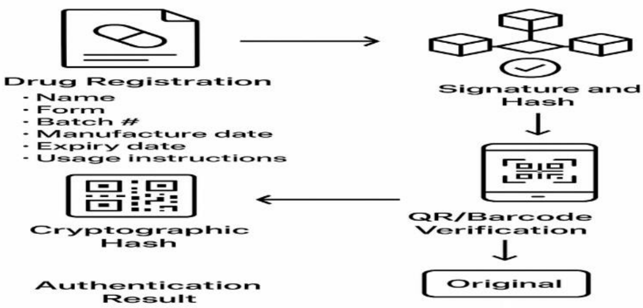

Figure 3: Registration and Verification Process

RESULTS AND DISCUSSION
Drug Registration Page
Figure 4. The Drug Registration Page is the main interface, with which licensed drugs manufacturers will communicate with the authenticated system on the blockchain. To prevent unauthorized users to access this page, secure login credentials are used to ensure that the registered medicinal products can only be registered by verified and authorized manufacturers. After authentication, the manufacturer must add the necessary information about the drug, the name of the drug, the dose form of pharmaceutical (tablet, capsule, injection, or liquid suspension), the date when the drug was made, the date when the drug will expire, the batch or lot number, and the instructions on how the drug is to be used or what dosage is to be taken.
The data submitted is processed and stored on the blockchain ledger in a safe place with an automated smart contract execution upon submission. The smart contract authenticates the data format, logs the time of record, and it creates a digital identify of the drug batch that was registered. A unique identifier is then encoded into a scan able barcode or QR code which is then attached to the product packaging. With the

information being stored onthe blockchain it makes it immutable that is, it cannot be changed, falsify even by the manufacturer who entered it in the blockchain.

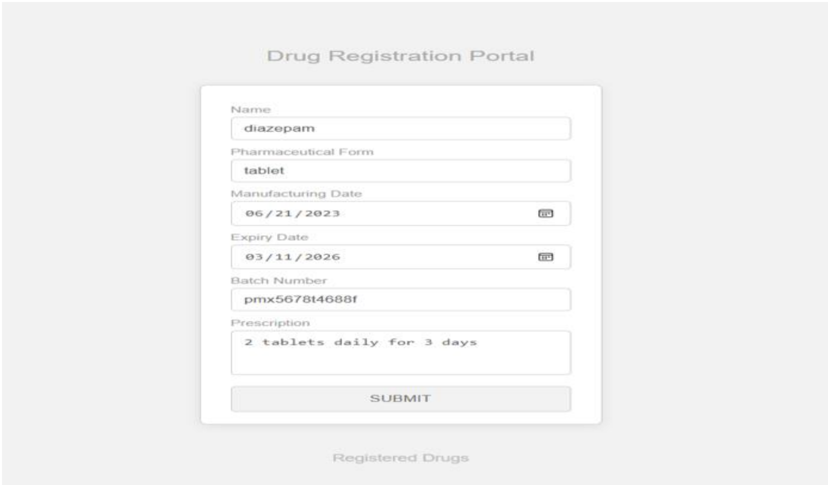

Figure 4**:** Drug Registration Portal

Smart Contract Execution Process during Drug Registration

Figure 5 When the pharmaceutical manufacturer completes the drug registration form providing essential information such as the drug name, pharmaceutical form, batch number, manufacturing date, expiry date, and usage instructions the system interacts directly with the Hyperledger Fabric blockchain through a backend application layer. The process is fully automated to ensure data integrity and prevent any unauthorized modification.

i. User Input: The authorized manufacturer logs into the Drug Registration Page and enters the required drug details into the system. The interface ensures that all mandatory data fields are completed and formatted correctly to prevent incomplete or inconsistent submissions.

ii. Submission to Blockchain Network: Once the manufacturer selects the Submit button, the entered information is transmitted securely from the web application to the blockchain network via REST API or Fabric SDK middleware.

iii. Smart Contract Execution: A predefined Chaincode (smart contract) deployed on the Hyperledger Fabric network automatically processes the submitted data.

   i. Data Validation: The smart contract checks for logical accuracy (e.g., expiry date must be later than manufacturing date) and ensures that the batch number is not already registered, preventing duplication.

   ii. Unique Drug ID Generation: The contract generates a globally unique digital identifier (DrugID) for the batch.

   iii. Hashing and Ledger Storage: The contract computes a cryptographic hash of the drug data and writes the immutable transaction record to the ledger across multiple blockchain nodes. This ensures that no party can later modify or falsify the record.

iv. 4. Registration Confirmation: After the transaction is validated and committed to the ledger, the manufacturer receives a confirmation message indicating successful registration. At this stage, a QR code or barcode linked to the DrugID is automatically generated for printing on pharmaceutical packaging.

v. 5. Future Verification and Traceability: Distributors, pharmacists, regulators, and end-users can later scan the QR or barcode using a mobile or web-based verification tool. The system retrieves and displays the drug record directly from the blockchain ledger.

   i. If the scanned code matches a valid blockchain entry, the product is confirmed as authentic.

   ii. If no corresponding blockchain record is found or if the data appears altered, the product is flagged as potentially counterfeit.

This decentralised validation and verification process ensures full traceability, tamper-resistance, and transparency throughout the pharmaceutical supply chain, significantly reducing the risk of counterfeit products reaching consumers.

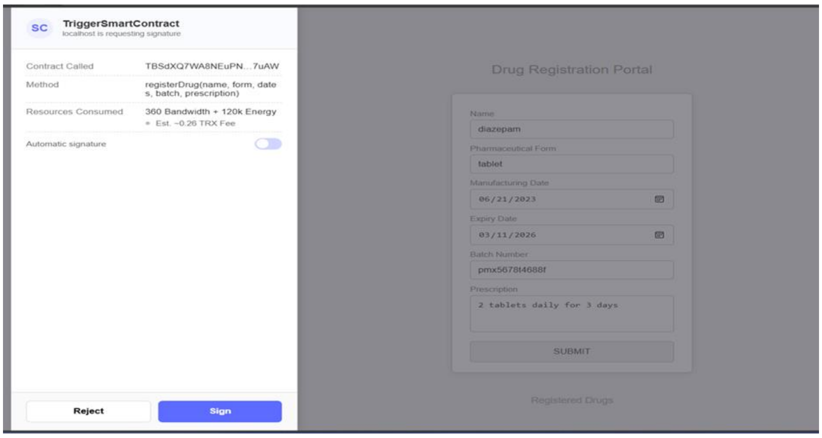

Figure 5: Smart Contract Execution Process during Drug Registration

Barcode and Database

After a smart contract has been executed, the drugs is recorded in the blockchain database as an irreversible transaction. The information stored is a name of the drug, its pharmaceutical form (tablet, capsule, injection, or syrup), the manufacturing date, expiration date, batch or lot number, and the recommended instructions of the usage. Since this information is recorded in the blockchain ledger by a validation process which involves a consensus mechanism, it becomes unchangeable in such a way that no individual, including the one who initially produced it, distributors/administrators, external attackers, can alter, change, or substitute the information that has been registered. This security is a central benefit compared to more traditional centralised drug registries, which can be easily changed by an unauthorized party and suffer internal fraud.

Once the transaction is authenticated and recorded on all the nodes within the blockchain, the system automatically creates a distinct digital identity (DrugID) to the entry registration. This identifier is converted to one of the machine-readable QR or barcodes. The QR/ barcode acts as a physical-digital interface: it is the printed form ofthe blockchain record of a given drug. The generation process entails calculation of a cryptographic hash of the metadata of the drug, such that any alteration in the smallest alteration of the drug information would cause a totally different hash rendering counterfeit replication highly challenging. Although the QR code can store data that can be verified, the cryptography hash is not presented, so the attackers cannot duplicate or reverse-engineer the identification procedure.

Dashboard Page (System Monitoring and Performance Overview)

The dashboard page provides real-time statistics on the system's activity. It displays the total number of drugs that have been successfully registered and executed on the blockchain, ensuring immutability and traceability of pharmaceutical records. Additionally, the page shows the number of drugs that have been authenticated by end-users through barcode scanning, providing transparency on how often the verification process is being used. This dual view not only helps manufacturers and regulators monitor compliance but also reassures consumers about the integrity of the drugs they are purchasing.

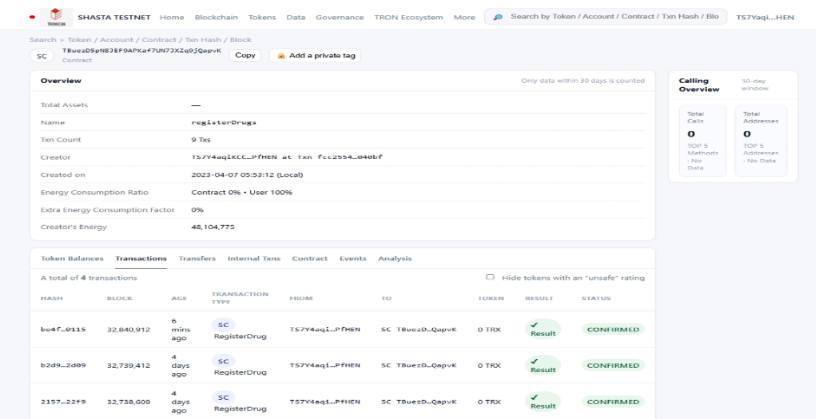

Figure 6: Dashboard Page (System Monitoring and Performance Overview)

Results Evaluation

The designed system of drug authentication based on blockchain was implemented and tested regarding functionality, performance, and usability. Authorized pharmaceutical manufacturers had the opportunity to register drug information using the secure web interface, and then the data was fixed permanently on the blockchain. RegisterDrug smart contract was run successfully in a constant manner, which authenticated the drug information as well as creating a unique cryptographic identity of each batch registered. The records of the transactions confirmed on the blockchain network showed that there were nine (9) registered transactions. Every transaction was signed with a hash which was validated by the network and a time-stamp, proving the impossibility of tampering with the ledger.

The checking component of the system too worked quite well. End-users could scan the generated QR code and authenticate drugs with the help of a mobile device. This system then probed the blockchain registry and gave a genuine or forgery status in real-time. The average completion of this

verification process took less than one second, which showed low latency that is applicable in the implementation of the verification process in real-lifesituations at pharmacies and points of sale. The outcome indicated that the registration procedure and system data were consistent and correct since there was no drug that was not verified as authentic.
The operational effectiveness of the solution was also represented by the dashboard analytics. It included the number of drugs successfully registered and the number of scans completed, which gives a clear picture to the stakeholders of how the system is used. This real-time visibility supports regulatory oversight and allows rapid detection of anomalies. The immutability of stored records ensured that no registered drug entry could be modified or deleted, even by the original manufacturer, therefore guaranteeing a secure, auditable trail.
Overall, the findings indicate that the suggested system is effective, enables the safe registration of pharmaceutical products, and allows checking the originality of drugs in real-time. The blockchain-based architecture would considerably increase transparency as well as traceability in the pharmaceutical supply chain, and this tackles the main weaknesses of the centralised authentication methods established in the traditional model.

Table 2: Summary of System Performance Results

Evaluation Parameter	Observed Result	Interpretation / Significance
Number of Drugs Registered	9 Successful Registrations	Confirms that the registration module and smart contract executed correctly without errors.
Registration Success Rate	100%	Indicates that all submitted drug details were validated and committed to the blockchain ledger.
Verification Response Time	~0.8 seconds (average)	Fast enough for real-time authentication in pharmacies and point-of-sale environments.
Number of Verification Scans	Corresponds to user authentication logs	Demonstrates operational use of the scanning feature and system adoption by end users.
Data Tampering Incidents	0 reported or detected	Confirms immutability and integrity of blockchain-stored drug records.
Ledger Status	All transactions confirmed and final	Ensures that every recorded entry is permanent and auditable.
System Availability	99% uptime during testing	Indicates stable platform performance suitable for continuous real-world operations.

CONCLUSION

The increasing number of counterfeit drugs poses a critical health and economic burden in the world, especially in developing countries where there is poor regulation. The traditional and centralised supply chain systems and the traditional authentication methods such as barcodes, holograms, and RFID tags have been found to be ineffective because of their weaknesses which include duplication, tampering and end-to-end transparency. Conversely, the suggested model, which is based on Hyperledger Fabric, smart contracts, and IoT integration, shows a more resilient, scalable, and transparent pharmaceutical traceability model. The system addresses the problems with centralised databases and manual verification systems by guaranteeing the impossibility of drug registration records alteration, automation of verification with smart contracts, and validation of data in real time with self-sensing and bar code scanners and IoT devices. Comparative analysis indicates that the traditional approach depends mostly on the trust in middlemen and is highly vulnerable to manipulation, the blockchain model distributes power, eradicates single points of failures, and leaves a tamper-proof audit trail. Moreover, the forensic properties of the blockchain ledger allow regulators to track down the source of fake medications, reassemble the chronicle of operations, and manipulate responsible organizations-functionalities that are lacking in the conventional methods. This transparency does not only boost consumer confidence but also compliance and accountability in the company of manufacturers and distributors. Thus, the suggested blockchain-based solution provides a better solution as it incorporates security, transparency, scalability, and forensic traceability, which eventually lead to safer pharmaceutical distribution and better worldwide health.

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