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Original Article

Traceability and Verification to Prevent Counterfeit Drugs: A Secure, Efficient Pharma Supply Chain with IoT-Enabled Blockchain and Smart Contracts

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Abstract *- Currently, the stakeholders involved in the pharma supply chain are manufacturers, distributors, retailers, and patients. The process is excessively complicated, offers minimum transparency and accountability, and appears poorly protected from counterfeiting. This paper proposes a novel integration of Internet of Things (IoT) sensors, blockchain technology, and Role-Based Access Control (RBAC), creating a transparent, immutable ledger that ensures the authenticity and visibility of drugs throughout the supply chain. IoT sensors provide real-time tracking of environmental conditions and moments of drugs, while blockchain technology ensures a secure, tamper-proof record of every transaction, enhancing traceability through the supply chain. Role-Based Access Control strengthens security by limiting access to sensitive data according to the roles of different stakeholders. The use of Smart contracts simplifies processes, as it removes intermediaries and ensures secure transaction histories. This integrated approach addresses counterfeiting and transforms pharmaceutical supply chain management by improving transparency, security, and efficiency. Enhanced blockchain performance facilitates more effective drug delivery, ultimately improving patient outcomes. By utilizing these advanced technologies, the proposed system significantly reduces risks associated with counterfeiting and supply chain disturbances, ensuring the delivery of safe and effective medications to patients.*

Keywords *- Blockchain, Internet of Things, Pharma supply chain, Role-Based Access Control, Smart contract.*

1. Introduction

Pharma Supply Chain Management (PSCM) is a complicated process that involves the transfer of legitimate drugs from the manufacturer to the customer while safeguarding their safety and efficiency. There are many players in this supply chain [1], such as raw material suppliers, manufacturers, distributors, retailers and patients. Temperature monitoring [2] and adherence to other cold chain standards while transferring drugs is one of the major challenges associated with PSCM; the other threat is the infiltration of counterfeit drugs [3] into the supply chain. The pharmaceutical supply chain faces significant threats posed by counterfeit drugs. Pharma fraud fake medicines are those in which such pharma fraud fake medicines are manufactured and provided in examples of these medicines that the products are real drugs, making the patients, healthcare providers, and consumers unable to identify them. Counterfeit drugs can enter the supply chain at different points, which can pose a threat to the health and safety of patients. The frequent problems are caused by mislabeling, quality standards and the existence of wrong or harmful ingredients. In 2016, the World Health Organization (WHO) [4] proposed the terms "substandard and falsified medicine," where substandard drugs are defined with regards to failing to meet quality standards, and falsified drugs refer to drugs that transact to misrepresent their source.

WHO estimates that about 30% of the world drug market is based on counterfeit drugs, where a sizable portion comes from developing countries. In Africa, Asia, and Latin America, counterfeit drugs constitute between 10-30% of the market. Globally, between 10-15% of drugs are counterfeit, and of this, 35-75% are produced in India [5]. As shown in Figure 1, a conventional supply chain management model shows drugs flow from manufacturers to distributors and from there to retailers who deliver to patients through pharmacies or hospitals. This traditional model doesn't give patients transparency about their medications' origins or delivery .

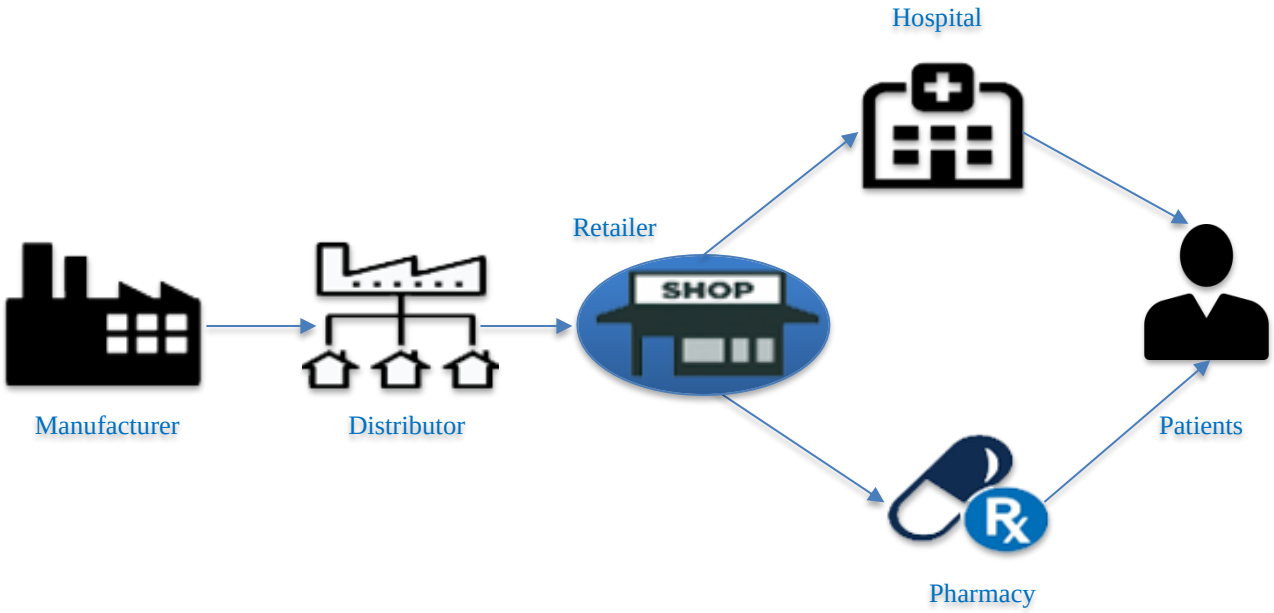

Fig. 1 Traditional drug supply chain management

Considering the increasing adversities, various stakeholders involved in the pharmaceutical supply chain must work together to ensure rigorous enforcement and employ stringent technologies to augment traceability and validation throughout the supply chain. This method allows for the smooth delivery of drugs to the patient safely and effectively.

The transport of drugs under very specific temperature-controlled conditions is another critical issue in PSCM [6]. Fever-induced responses and reactions to heat help control many diseases, and several medications, especially injectables and vaccines, need to be held within specific temperature ranges to retain their potency. If not transported under the appropriate temperature, they can be ineffectual or even dangerous. Transport delays, extreme weather, and poor handling can affect drug quality and make them unfit for human consumption.

Conventional PSCM suffers from many issues, such as lack of visibility, lack of real-time data, lack of smooth collaboration between the parties and manual processes. This results in delays, inefficiencies, rising costs, and waste of energy and other resources. Worldwide, automating demand forecasting enhances customer satisfaction and operational efficiency.

The PSCM will be challenged where collaboration and flexibility become imperative, and technologies like IoT and blockchain will start engaging more strongly in the PSCM. Such visibility and communication challenges can be tackled using these technologies, creating a stronger and more efficient supply chain ecosystem. This paper presents a new method that combines blockchain technology to enhance the security level of PSCM. Our system has the ability to deliver a drug securely and provides all participants with a decentralized, transparent and auditable ledger. It makes records tamper-proof while eliminating the need for centralized verification due to the decentralized and immutable nature of the blockchain.

While some people think about blockchain only as a mechanism for diffused digital currencies such as Bitcoin [7], its applications go much beyond cryptocurrency. Blockchain architecture versatility can be seen in exchanges, contracts, movement frameworks, and payment channels. Technology such as blockchain technology focuses on increasing transparency, security and efficiency in Supply chain management from warehouse to delivery and payment. Originally developed as a tool to implement an automated way of entering into contracts under the stipulations of a blockchain, smart contracts [8] are a pillar of blockchain technology that creates trust and provide a means of verification without the reliance on a third party by executing the terms of the contract themselves.

Role Based Access Control (RBAC) [9] eases access to network resources by assigning roles instead of individual permissions thus contributing to security in Pharmaceutical Supply Chain Management (PSCM). Combining Blockchain and IoT with RBAC introduces the needed transparency, trust, and efficiency. By virtue of the immutable nature of the blockchain, data is secured, while IoT sensors can track the conditions of transported drugs, such as temperature and humidity. Smart contracts help automate processes which allow stakeholders to confirm the terms of the smart contract,

ensuring the authenticity, quality, and legitimacy of the drug, thereby changing the customer experience as soon as the drug is purchased.

When integrated into IoT, the proposed blockchain-based approach can solve major challenges in PSCM, such as fake drugs, temperature inspections, and process inefficiencies. The system cultivates trust between stakeholders while providing patients with real and good-quality drugs by creating a safe and transparent ecosystem. That is a crucial step in ensuring the effectiveness of PSCM and the protection of public health through combatting the risk of counterfeiting and poor storage conditions for pharmaceutical products.

The purpose of the paper is

1. To introduce an innovative supply chain management solution utilizing smart contracts, safeguarding the rights and interests of manufacturers, distributors, and patients are protected. This solution will provide a detailed architecture and system design while tracking key events throughout the supply chain.
2. To offer a solution that removes the reliance on third-party proof, guaranteeing independent verification of transactions and drug quality throughout the supply chain.
3. Create a system integrating IoT sensors within shipment containers to monitor and detect breaches or violations, automatically recorded and logged into a smart contract, ensuring transparency and accountability during shipping.

The remaining paper is structured as follows: Section 2 analyses different methods to tackle the issue of drug counterfeiting. Section 3 describes the smart contract design for the PSCM solution, including the implementation and testing processes. Section 4 provides a performance evaluation of the smart contract. Finally, Section 5 presents our conclusions.

2. Literature Review

This section offers an overview of the blockchain-related works covering the pharmaceutical supply chain domain. Given the novelty of the use of blockchain technology in this domain, specific details on its implementation are absent in most of the papers studied, which concentrated on concepts, initiatives and efforts. A blockchain is a distributed ledger based on decentralization that keeps a record of transactions. The blockchain is an immutable record of timestamps of transaction data, with hashes of a previous block cryptographically signifying the next block (with a unique number). Blockchain technology presents many benefits for supply chain management. This offers several advantages; one of them is increased transparency. A single, immutable record of transactions that everyone in the supply chain — manufacturers, suppliers, distributors, retailers, etc. — can access over a shared platform in real time. This transparency reduces the risk of fraud, lowers human errors, and ensures all parties have the same information. These smart contracts are automated and code-based contracts to automate and enforce contracts among the supply chain. Enhancing processes and shortening wait times by eliminating intermediaries due to automation. Blockchain also increases traceability, with 100% pristine data on where each product has travelled in the supply chain. This can be especially important in sectors where product traceability is key, for example, food and pharmaceuticals.

Moreover, blockchain improves security with the help of consensus methods [10] and cryptographic methods. It increases the strength and reliability of supply chain infrastructure through a decentralized technology that is resilient against single points of failure and unauthorized access. Some areas where blockchain technology has the potential and will impact include transparency, traceability, efficiency, security, and supply chain management.

In this paper, authors [11] propose a safe and transparent drug supply chain system based on the ideation of Blockchain technology. The entire complex of drug distribution can be traced, and the criteria are stored in a distributed, immutable ledger so that the pharmaceutical industry enjoys enhanced traceability and authenticity, thus modifying the risk factors relating to fake drugs. This way, not only does it ensure the integrity of the data, but it also creates a trust network where only trusted people can write data on the blockchain, giving the guarantee of protection for the health and life of consumers. In [12], authors reported disturbing statistics such as 10% of drugs being counterfeited around the world, making a total of $200 billion, which poses a significant risk to public health. So, they used OCR to read the medicine details to verify originality. Through population awareness and data that will be open to the public, this enterprise is intended to protect people from the harmful effects of the illegal explosion of counterfeit drugs, thus securing the safety and well-being of the public.

This paper investigates the use of IoT and blockchain technology as a potential solution [13] to address the issue of fraud and abuse within the pharmaceutical supply chain. This is the new age of drug governance, where a repeated chain of radio frequency waves provides a ledger of the drug trade from the source to the end consumer, i.e., the patient, thereby increasing the degree of reliability with which healthcare can function. Such transformation has the potential to meet the urgent need to preserve pharmaceutical integrity, resulting in a more robust, reliable, and secure pharmaceutical supply chain.

The proposed decentralized system leveraging the advanced functionalities of the blockchain technology with the QR-encrypted application mechanism, specially designed

based on the Ethereum platform, can efficiently trace and track the counterfeit medicines propagating in the pharma supply chain [14]. The acute problem of drug counterfeiting gives an opportunity for pharmaceutical companies to leverage a proven strategy to protect the identity of their drug and also protect the health of the public. Using blockchain helps ensure transparency and accountability in the supply chain, as it reduces duplicate drugs from being transmitted via the supply channel and makes the healthcare ecosystem safer.

In [15], the authors described that fake medicines pose health, safety, and financial risks to patients, especially in developing and undeveloped countries. An urgent and straightforward solution is needed in the wake of these challenges: little guidance on managing knowledge is available, few specialized instruments are in place, and detection devices have yet to become truly progressive and available. A good prior work on detecting counterfeit drugs was based on using an open-source framework, Hyperledger. The potential significance of the development of Solutions provided by Hyperledger is to ensure an effective mechanism for identifying and preventing the circulation of fake medications by tackling long-standing issues in the healthcare industry. Despite the optimistic view on IoT nationwide, contradictory expectations have been identified among small and large-scale enterprises [16]. Many technologies, including RFID and the EPC global network, have been developing, and the application of these technologies is widely adopted with an obvious contribution to supply chain efficiency. This work comprehensively surveys the most influential research on supply chain management and the barriers organizations face in adopting IoT technologies. In closing, this benefits scope and the conceptual framework suggest that IoT solves complex business management problems, resulting in better supply chain performance, more profitability, and increased customer satisfaction.

A decentralized, transparent, and secure system is needed due to the problem of limited Visibility, Ineffective communication, demand prediction, cross-border logistics [17], elevated operation, and improper environmental parameters found in the PSCM. This paper proposes a problem-solving method to address transparency and efficiency issues relating to drug supply chains in pharmaceutical supply management using smart contracts, blockchain and IoT technologies.

3. Smart Contract Design of Pharma Supply Chain Management

Figure 2 represents the architecture of a blockchain-based Web application for pharma supply chain management, showing the interaction between smart contracts, an Angular app (used for client-side communication), front-end technologies, and stakeholders.

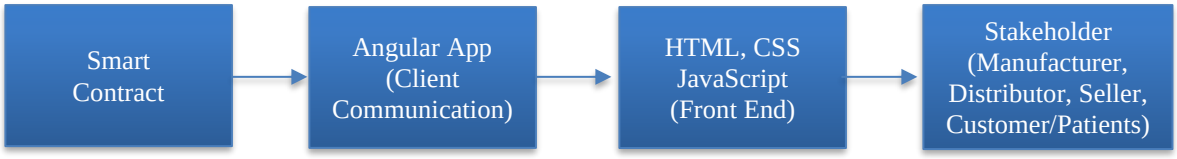

Fig. 2 Blockchain-Based Web Application Architecture with Smart Contract Integration

Smart Contract: Smart Contracts are self-executing programs stored on the blockchain which run automatically when the condition is met. Here in this architecture, smart contracts are executed when the condition is met, like manufacturing drugs, adding manufacturer, distributor etc. or updating the supply chain status. These activities are transparent, immutable, and tamper-proof, confirming faith and efficiency in the supply chain.

Angular App (Client Communication): Angular is the most popular front-end framework for building dynamic web applications. It serves as the bridge between stakeholders and the smart contract, allowing communication with the blockchain-based backend. It manages client requests and sends them to the smart contract for execution.

HTML, CSS, JavaScript (Front End): These are the fundamental technologies for creating the front end of a web application. They define the User Interface (UI) and control the app's behavior, styling, and structure with which stakeholders interact.

JavaScript allows interaction, while HTML structures the content and CSS styles it. These are the technologies used for creating the front end of a web application. JavaScript allows for interaction, while HTML structures the content and CSS styles it.

Stakeholders: These Stakeholders (Manufacturers, Distributors, Sellers, Customers or Patients) use the front-end application to interact with the smart contract, and each stakeholder is associated with specific smart contracts that perform different tasks depending on their role in the supply chain. As shown in Figure 2, a detailed smart contract system design with operations that enable decentralized and transparent supply chain management is proposed, as illustrated in Figure 3.

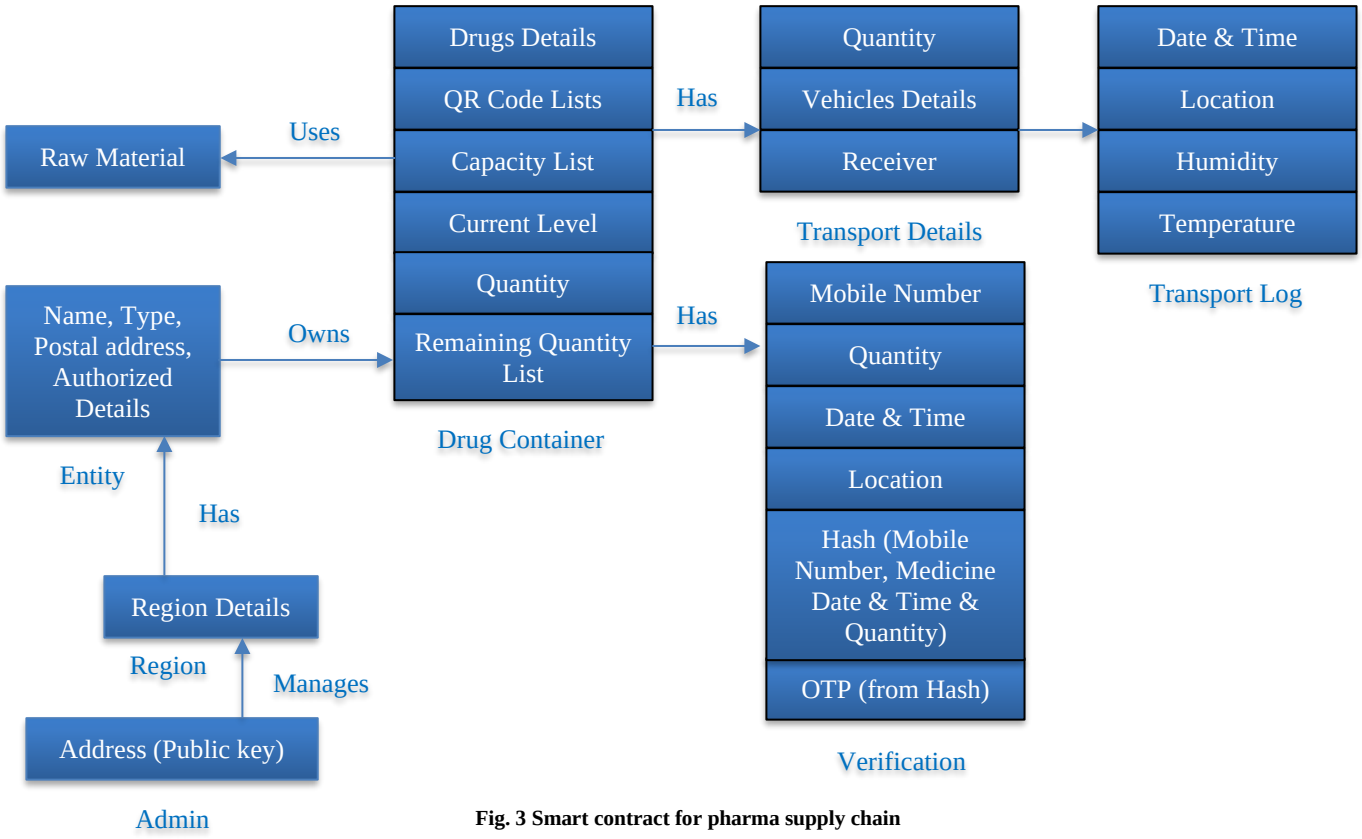

Fig. 3 Smart contract for pharma supply chain

The system components are as follows:

1. Raw Material: This block captures the essential details of the raw materials used in drug manufacture. It includes name, type, postal address, and authorized details. This stage characterizes the initial phase of the supply chain, where raw materials are identified and verified to ensure validity. Including authorized details guarantees the credibility and trustworthiness of the raw material suppliers.

2. Drugs Details: This block manages detailed information about the drugs manufactured from the raw materials. It includes:
   QR Code Lists: Unique identifiers allocated to each drug batch. Capacity List: The amount that a container holds to transport the drugs.

   Current Level: The present inventory level of the drug batch. Quantity: The number of drugs manufactured in each batch. Remaining Quantity List: Details of the remaining stock after deliveries.

3. Transport Information: This block logs intelligence about the movement of the drugs from one location to another. It could include: Quantity: The number of drugs manufactured in the specific mode of transport.
Vehicles Info: Information about the vehicle used for transportation Receiver: The one receiving the drugs.

4. Environmental Data: This will help to monitor the environmental parameters in which the drugs are transported to make sure they are safe and efficient. Included are: Date & Time: Timestamp of the time and date of when the data was recorded. Place: Region where the data was collected. Temp & Humidity: Temperature and Humidity conditions encountered during transit.

5. Verification Information: This block is responsible for the last-mile delivery of the drugs to the consumer, such as patients. It guarantees the proper delivery of the drugs and includes:

Mobile Number: Contact number of the receiver.
Quantity: Quantity of drugs received by the receiver.
Date & Time: Timestamp of when the drugs were received.
Location: Geographic location of the receipt.
Hash: A cryptographic hash combining mobile number, drug details, date and time, and quantity to ensure data integrity.
OTP (One-Time Password): A security code generated from the hash for an extra layer of security verification.

6. Address (Public Key): A public key is used to make cryptographic verification; each transaction is assigned a public key to ensure security on the blockchain. This means every transaction has to be secure and verifiable.

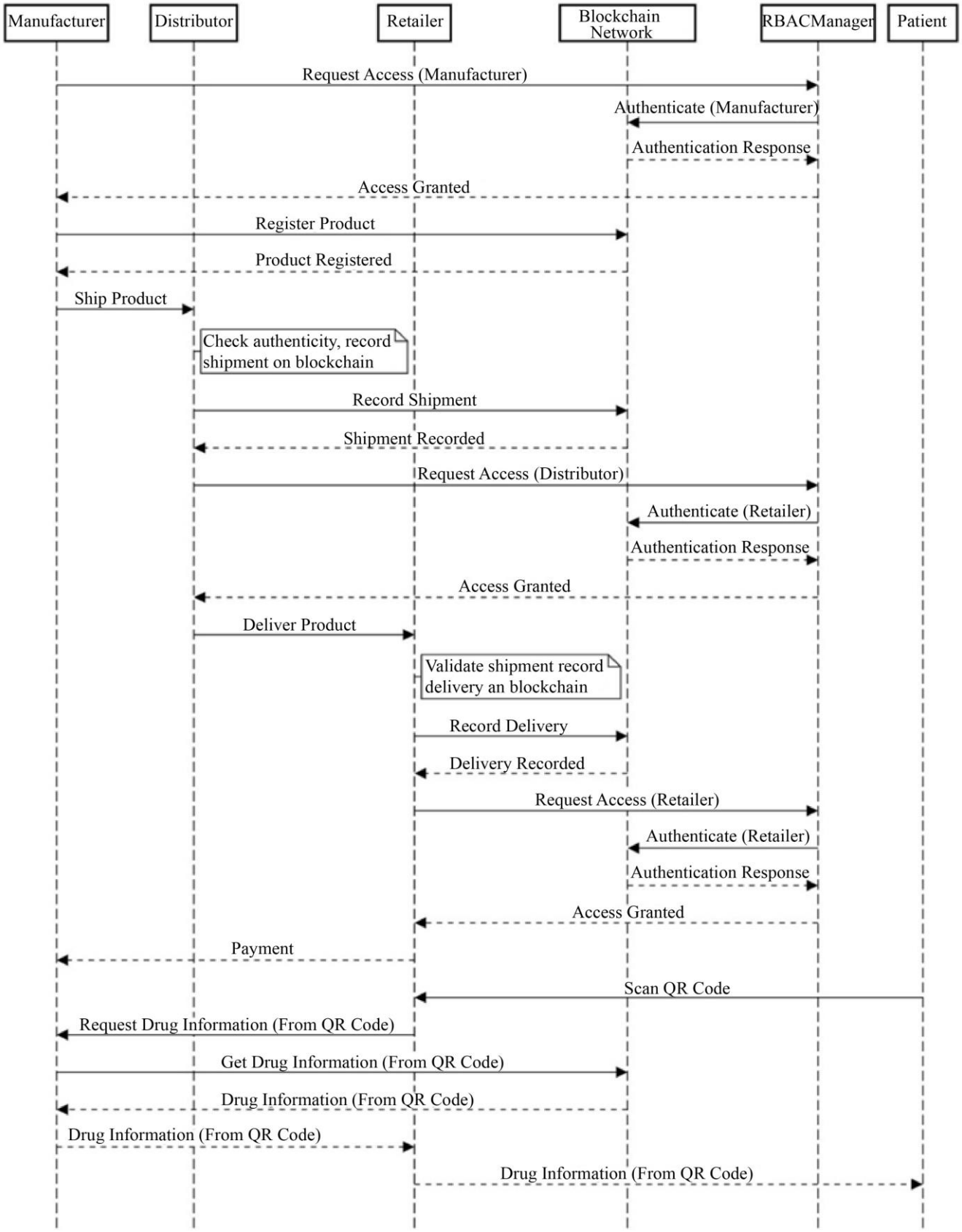

Fig. 4 Sequence diagram of pharma supply chain management

3.1. Implementation

This section gives the main implementation details and analyzes how system stakeholders and the smart contract actually interact with each other functionally, as well as giving a sequence diagram as depicted in Figure 4. Blockchain Network and RBAC Manager bring transparency and authenticity to the pharma supply chain end-to-end. The manufacturer requests access for registration, is authenticated and registers the product on the Blockchain Network upfront. This product is shipped to the distributor, who checks and registers the shipment. The distributor asks for access, gets authentication and brings the product to the retailer. As the retailer receives the drug, it verifies, logs its receipt and scans the QR code for drug information from the Blockchain Network, once it is actually a verified one. Last, this information is given to the patient by the retailer, and it is controlled and validated at each and every stage.

Implementation Steps:

- The function 'create ()' initializes the smart contract by setting the super-admin and generating the first region, "India" with the super-admin as the region's administrator. When the smart contract is first deployed, a Region is created, and the administrator will add all the stakeholders in that region, assigning them a unique wallet address to identify them within the region.

The smart contract provides functions such as 'addManufacturer ()', 'addDistributor ()', and 'addSeller ()' that allow the administrator to assign roles and permissions to stakeholders within the region. When a stakeholder is added, roles/privileges are allocated to them using functions such as activateManufacturer (), activateDistributor () and activateSeller () to allow them to transact and perform their duties.

With the same line of code, the administrator can deactivate stakeholders such as deactivateManufacturer (), deactivateDistributor (), and deactivateSeller (), and they will not be able to perform their transactions.

This stepwise representation of participants, enabling them to be added, activated, and deactivated, ensures a controlled, safe environment for all parties involved and secures transaction verification within the blockchain network.

The 'createDrugContainer ()' function allows manufacturers to input details from raw materials, creating a DrugContainer that includes full information about the manufactured drug, such as name, manufacturing date, expiry date, capacity, quantity, remaining quantity, raw material used, and supplier name as shown in Figure 5.

The manufacturer of drugs chooses a transaction type, as shown in Figure 6, to create a new container for first-time manufacture or a transfer container for delivering a drug to a particular distributor, as well as all relevant details and quantities. The capacity indicates how much a container can transport the drug.

Once the container is created, a QR code will be generated with the Hash generated like the below in Figure 7, containing all the necessary information to track and trace the drug manufactured.[7] An embedded QR code that tracks the drugs in the supply chain.

getDrugContainer() function When drugs are sent to the distributor, it helps to have complete data of all the drugs and their container with the address of the container.

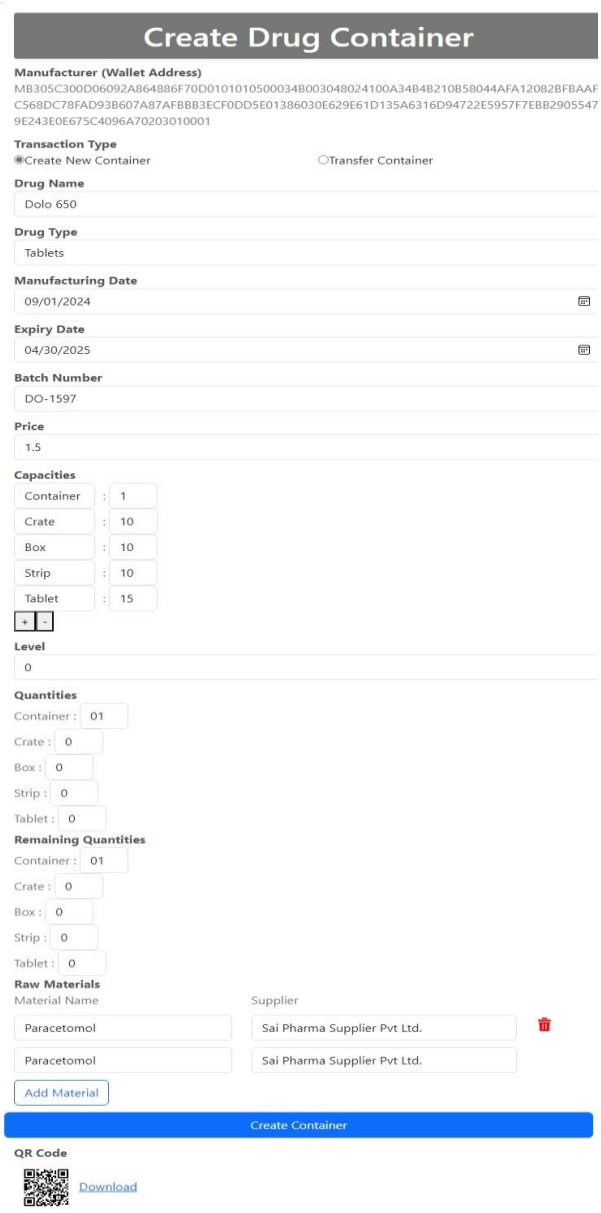

Fig. 5 Drug container

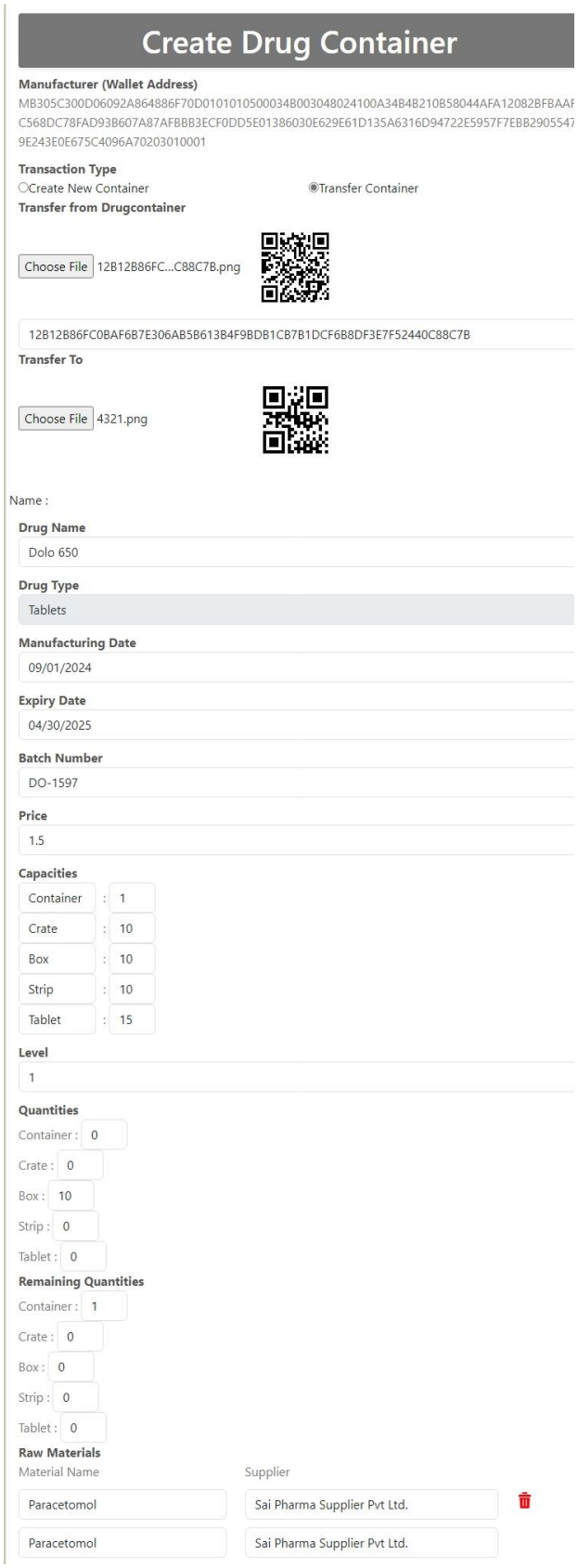

Fig. 6 Transfer drug container

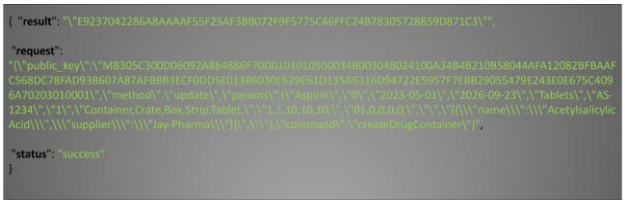

Fig. 7 Resultant hash

It also keeps transportation logs, such as the vehicle type, registration number, the dispatch date, the receiver's name, and the address of a live tracking device installed in the vehicle, as shown in Figure 8.

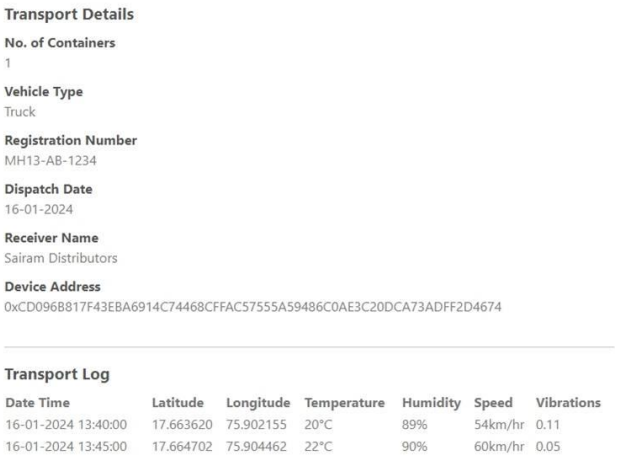

Fig. 8 Transportation details

It is a system that allows tracking of the location and timestamps of the vehicle in the supply chain, thus tracking the vehicle on a map in real-time.

Parameters like latitude, longitude, temperature, humidity, speed, and vibration are recorded in real time, providing complete supply chain transparency. It provides tracking of the movement of the drugs. It provides life-threatening updates to the stakeholders on the status and movement of these drugs while in transit and the potential for environmental risk in transit.

To guarantee that drugs (predominantly vaccines) remain safe and effective, they are limited to a temperature range (0°C to 5°C) as they pass through the supply chain. In case the temperature goes above or below this range, the system will immediately send an email alert to all stakeholders concerned about the issue. It is an essential tool to ensure everything is in order so that you get notified within the time you are notified via email about any temperature issues, and it raises an alert. The system is integrated with Google Maps, which allows stakeholders to track the exact position of the vehicle in real-time and record the temperature, humidity, speed, and vibration status during transit. Full visibility over the shipment is central to this integration, allowing stakeholders to monitor

the transportation process from start to finish and react quickly if needed. Such steps squash time taking, improve supply chain productivity, and keep the medicines, products, or items out of risk of potency loss. When patients purchase medicine at a pharmacy or hospital, they scan a QR code on the packaging. This QR code contains details like the type of medicine, batch number, manufacturing and expiry dates, and price. The pharmacist then enters the quantity you need and adds it to your bill.

To verify the sold medicine, the pharmacist must enter the customer's mobile number to receive a one-time password (OTP) for date, time, and location detection, as shown in Figure 9. After entering the OTP, if the pharmacy or hospital has enough medicine stock, it is verified, and you can scan the QR code to check all the information, as shown in Figure 10.

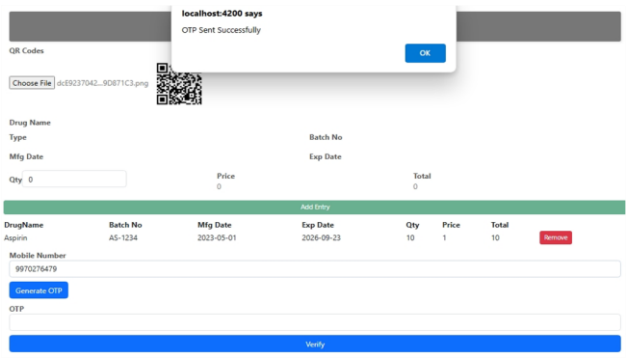

Fig. 9 OTP details

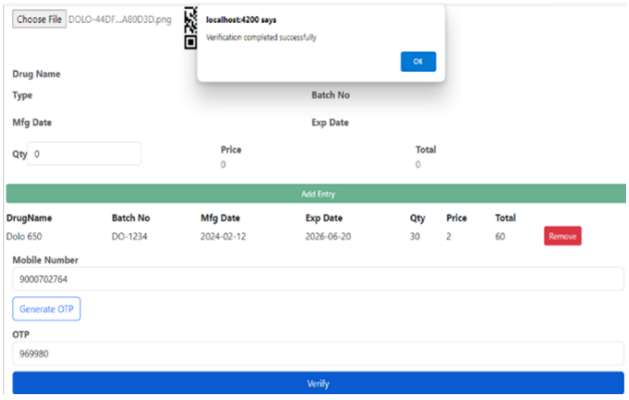

Fig. 10 Verified Drugs' Sold Details

In addition, the Contract Viewer, as shown in Figure 11, allows tracking everything from the manufacturer of the medicine to the sale of the medicine to the end patient. From the smart contract viewer, all blockchain aspects will log each step in a recorded, transparent line that the user crosses to verify the supply chain continuity. In this manner, it ensures that each action taken is as per the rules and no action has been carried out without proper authorization or on false pretenses. Smaller time intervals for real-time information can be checked by any participant, creating a previously unattainable level of trust and transparency. It also contributes to compliance management and fraud prevention. Additionally, to view the average time to execute functions and how much data was moved (per transaction). This helps you build a more trusted and efficient system for tracking.

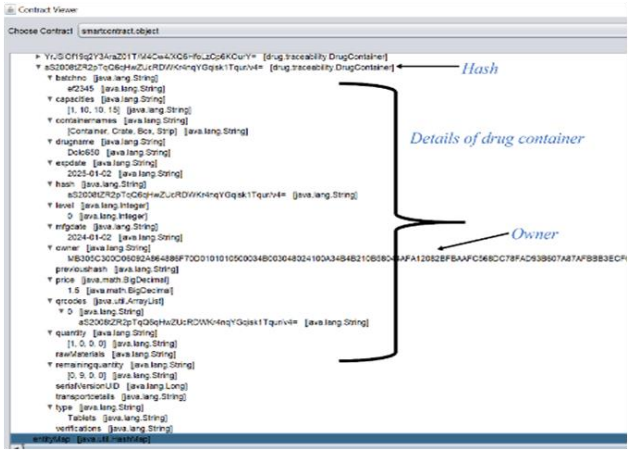

Fig. 11 Smart contract viewer

4. Performance Evaluation of Smart Contract

This article presents how to evaluate smart contract performance both on the time cost of function execution and the size of data sent per transaction. Such metrics serve as critical indicators of the capability and scalability of the underlying blockchain network that allows the supply chain operations to work. The average time to run each function of the smart contracts is illustrated in Figure 12. Now, you can see that the function createDrugContainer () has a higher execution duration than other functions. Knowing the reasons behind this longer execution time can help decide optimization strategies to improve the entire smart contract system's efficiency.

On the other hand, the orange line in the same figure indicates the amount of data transmitted per transaction. The function "addRegionAdminitrator ()" plays a large part in the amount of data it sends on the blockchain network. This function would be where they are likely adding administrative privileges for a specific area of the supply chain network. This data transmission boost related to this function underscores the need for effective management of data and utilizing the network bandwidth to avoid network congestion and promote timely transaction processing. Since the throughput (number of transactions settled) and latency (time to finalize a transaction) of the blockchain are greatly enhanced by processing the sensor data locally and sending only essential data to the blockchain by filtering the data close to the source, it reduces the number of transactions that are sent to the blockchain which means that more transactions can be handled by the blockchain system. As a result, only relevant information gets transmitted, thus increasing throughput. This reduces transaction size and frequency, increasing the transaction propagation time and confirmation on the

blockchain while also helping to improve latency. This leads to reduced confirmation times and improved suitability for real-time applications within the system. This way improves the efficiency of a blockchain by avoiding the duplication of information.

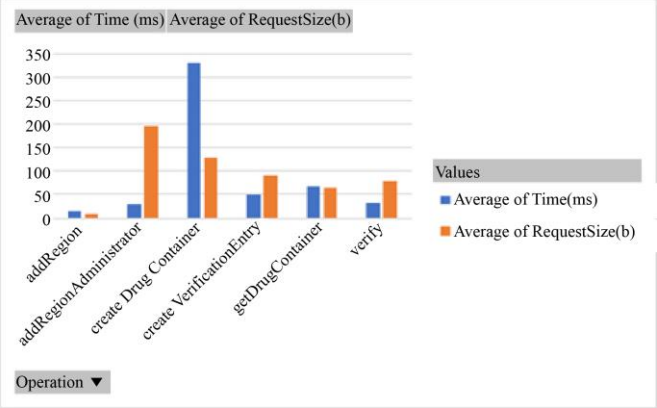

Fig. 12 Performance analysis of the smart contract

5. Conclusion

This article proposes a novel pharma supply chain management system based on IoT and blockchain technology to combat the problem of counterfeit drugs. It offers special environmental conditions monitoring applicable to individual drugs. Powered by decentralization, an immutable ledger, and hashing techniques unique to blockchain technology, our system allows data transfer between devices to become part of a private ecosystem without intermediaries while increasing accountability through automated smart contracts and role-based access control. The framework allows patients to authenticate their medication without the necessity to break packages; on account of the terroir, the producers will need to ensure top quality. Ultimately, this holistic method requires a new pharma supply chain management paradigm that positively impacts patients, improves risk management, enhances drug delivery efficiency, and paves the way for generic applicability over domains where the supply chain model can be identified.

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